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(54) **Title**: MECHANICAL GASTRIC BAND WITH CUSHIONS

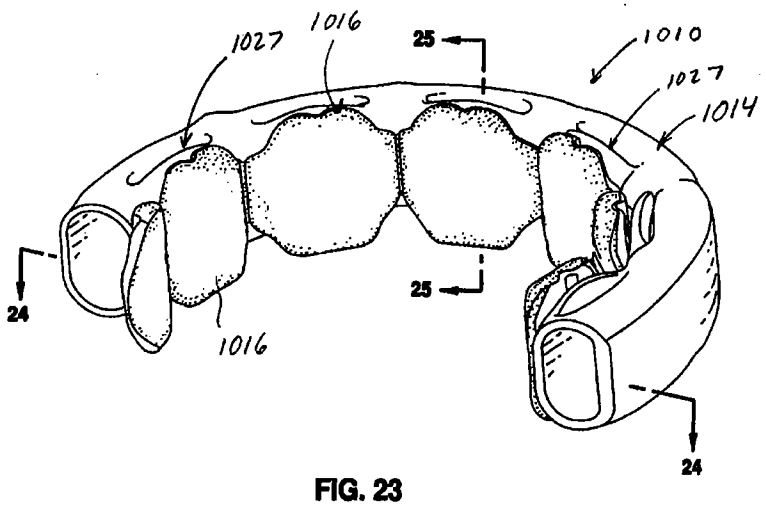

FIG. 23

(57) **Abstract**: A system for regulating the functioning of an organ or duct generally includes an implantable band structured to at least partially circumscribe an organ or duct and an actuating mechanism operable to effect constriction of the band. The system further includes a plurality of incompressible cushion segments defining a substantially star-shaped inner circumference of the band, the star-shape effective to prevent pinching and necrosis of tissue during adjustment.

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MECHANICAL GASTRIC BAND WITH CUSHIONS

By Inventors Tiago Bertolote and Pierre Fridez

RELATED APPLICATION

This application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/103,153, filed on October 6, 2008, the entire disclosure of which is incorporated herein by this reference.

BACKGROUND

This invention relates to surgical devices for regulating or controlling an organ or a duct, for example, a gastric banding system.

Obesity is well recognized as a serious health problem, and is associated with numerous health complications, ranging from non-fatal conditions to life threatening chronic diseases. According to the World Health Organization, debilitating health problems associated with obesity include respiratory difficulties, chronic musculoskeletal problems, skin problems and infertility. Life-threatening problems fall into four main areas: cardiovascular disease problems; conditions associated with insulin resistance such as type 2 diabetes; certain types of cancers, especially the hormonally related and large bowel cancers; and gallbladder disease. Beyond these physiological problems, obesity has also psychological consequences, ranging from lowered self-esteem to clinical depression.

Surgical intervention is sometimes indicated for people suffering from the effects of obesity. Such intervention not only mitigates the myriad health problems arising from being overweight, but may reduce the risk of early death of the patient. Left untreated, morbid obesity may reduce a

patient's life expectancy by ten to fifteen years.

SUMMARY OF THE INVENTION

A system for regulating an organ or duct, for example, the functioning of an organ or duct, is provided. The system generally comprises an implantable band having a first end and a second end, a distal region and a proximal region, and a connector configured to couple the first end with the second end such that the band is formable into a loop configuration. The band is structured to circumscribe, or at least partially circumscribe, an organ or duct, for example, a stomach. The system further comprises a mechanism for enabling adjustment of an inner circumference of the loop configuration to effect constriction of the organ or duct.

For the sake of simplicity, and in no way intended to limit the scope of the invention, the "organ or duct" will hereinafter typically be referred to as a "stomach" and the system will be described as a gastric band system. The band is structured to circumscribe an upper portion of a stomach to form a stoma that controls the intake of food to the stomach. It is to be appreciated that although the invention is hereinafter typically described as pertaining to a gastric band system for application to a stomach, for example, for obesity treatment, the system, with appropriate modification thereto, can be used for regulating or controlling any organ or duct that would benefit from application of the present system thereto.

Once the band is implanted about the stomach, the size of an inner diameter of the band can be adjusted to provide the desired degree of restriction. Techniques for determining appropriate adjustment of gastric bands, timing

and amount of adjustments, are known in the art and therefore will not be described in great detail herein.

Advantageously, in a broad aspect of the invention, the system may be structured to substantially prevent or at least reduce the occurrence of pinching of the body tissues, for example, the tissues of the stomach, during constriction or tightening of the band.

For example, in a specific embodiment, the system further comprises a contact region located between the first end and the second end of the band which is structured and functions to progressively move tissue, for example stomach tissue, during tightening of the band, without entrapping the tissue.

The contact region may comprise plurality of first segments and a plurality of second segments arranged in a generally alternating manner along the proximal (e.g. stomach-facing) region of the band. The first segments may comprise relatively wide, substantially incompressible cushion segments, and the second segments may comprise relatively thin, elastic tension segments. During constriction of the band, adjacent incompressible cushion segments form a progressively narrowing angle, for example, a substantially V-shaped surface. A tension segment is located between the adjacent cushion segments and forms the vertex of the angle or V.

In some embodiments, the cushion segments and tension segments form an inner circumference of the loop configuration having a generally star-shape, defined by the contact region. Deformation of the star-shape during adjustment substantially or entirely prevents pinching of

tissues, as the cushion segments roll forward one another without gaps there-between thus pushing the tissue inwardly.

More specifically, in some embodiments, the contact region defines alternating convex stomach-facing surfaces and concave stomach-facing surfaces. The convex organ facing surfaces may be defined by the cushion segments and the convex organ facing surfaces are defined by the tension segments located between adjacent cushion segments. During constriction of the band, the convex organ-facing surfaces may maintain their shape while folding at the tension segments inwardly toward one another. This mechanism and structure causes the tissues of the stomach to be pushed outwardly from the band constriction without the tissues becoming entrapped and/or pinched by the contact region.

In addition, the structure of the contact region, including cushion segments and tension segments, may be advantageously structured to maintain mechanical stability of the band. For example, the tension segments provide a means for maintaining positioning of the cushion segments and by substantially preventing the contact region of the band from creasing, folding or rolling out of position while the band is implanted in the body around the duct or organ, for example, the stomach.

In some embodiments, the contact region comprises a membrane, for example, a somewhat tubular-shaped elastic membrane encompassing, secured to or defining the cushion segments. In one embodiment, portions of the membrane may form the tension segments between adjacent cushion segments.

In one embodiment, the cushion segments are formed of individual incompressible molded elements in contact with or spaced apart from one another, and affixed to the membrane.

The cushion segments may be spaced apart by portions of the elastic membrane which are stretched under tension.

The cushion segments may be located on an internal surface of the membrane or alternatively may be located on an external surface of the membrane. In one embodiment, the cushion segments are located on an external surface of the membrane and are overmolded to the membrane.

In another feature of the invention, membrane may include structure, for example, corrugations or indentations, for facilitating expansion of the membrane during adjustment of the loop. For example, such corrugations can be located and structured to minimize the force required to elongate or stretch the membrane in the radial direction during tightening of the band. The corrugated surfaces of the membrane reduce membrane deformation energy by allowing the membrane to unfold rather than stretch during adjustment.

The mechanism for enabling adjustment may comprise an electronic interface, for example, an implantable electronic interface, connected to the band, and a control, for example an external control unit, capable of communicating with the interface to regulate the constriction of the band about said organ or duct.

These and other features of the present invention may be more clearly understood and appreciated upon consideration of the following Detailed Description and the accompanying Drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a schematic representation of one embodiment of the present invention, the system including a band including a contact region, an interface including an antenna/controller pod, and an external control.

Fig. 2 shows a perspective, cutaway view of the contact region shown in Fig. 1.

Fig. 3 shows a perspective view of the contact region shown in Fig. 1.

Fig. 3A shows a cross-sectional view of the contact region taken along lines 3A-3A of Fig. 3.

Fig. 4A shows an elevation view of the contact region shown in Fig. 1.

Fig. 4B shows an elevation view of an alternative contact region in accordance with another embodiment of the invention.

Fig. 4C shows a perspective view of the alternative contact region shown in Fig. 4B.

Fig. 5A shows a cross-sectional view of the band shown in Fig. 1.

Fig. 5B shows a cross-sectional view of the band taken along lines 5B-5B of Fig. 5A.

Fig. 5C shows a perspective, cutaway view of the band in a fully open position.

Fig. 5D shows a perspective, cutaway view of the band in a constricted position.

Figs. 5E and 5F are schematic representations of an amplified adjustment feature of an embodiment of the present invention.

Fig. 5G and 5H are simplified schematic representations of another embodiment of the invention.

Figs. 6A through 6C show plan views of the band at different levels of constriction.

FIG. 7 is a partial perspective view of a screw thread portion of a tension element useful in the band of the system of the invention.

FIG. 8 is a perspective view of an entire tension element shown in Fig. 7.

FIG. 9 is a perspective view of the tension element of FIG. 8 coupled to a rigid distal peripheral portion in the band of the system of the invention.

FIG. 10 is a perspective view of the band of the system in a straightened configuration and located within a trocar to facilitate implantation.

FIG. 11 is a cross-sectional view of an actuator housing on an end of the band.

FIG. 12 is a perspective view of an actuator in the housing shown in Fig. 11.

FIG. 13 is a perspective of the tension element engaged with the actuator shown in Fig. 12.

FIG. 14 is a cross-sectional view depicting the construction of the actuator shown in Fig. 12.

FIG. 15 is a cross-sectional view depicting the construction of a reference position switch useful in the system of the invention.

FIGS. 16A and 16B are perspective views illustrating a clip used to close the band of the system of the invention.

FIG. 17 is a perspective view of the antennae/controller pod of the system shown in Fig. 1.

FIG. 18 is a cut-away view of the interior of the implantable antenna/controller pod.

FIG. 19 is a schematic view of telemetric power and control circuitry useful in systems of the invention.

FIG. 20 is a view of a signal strength indicator portion of the control shown in Fig. 1.

FIG. 21 is a schematic diagram illustrating placement of the implantable portions of the system of the invention.

Each of FIGS. 22A-22H is a view illustrating steps in a method of laparoscopically implanting the system of the present invention.

Fig. 23 is a perspective view of a contact region including a membrane and overmolded incompressible cushions of a gastric band of the present invention.

Figs. 24 and 25 are cross sectional views of the contact region shown in Fig. 23 taken along line 24-24 and line 25-25, respectively.

DETAILED DESCRIPTION

Turning now to Fig. 1, an embodiment of a system of the present invention is generally shown at 10. In one aspect of the invention, the system 10 is useful for regulating the functioning of an organ or duct (not shown) for example, a stomach. In one embodiment, the system 10 is a gastric banding system useful in the treatment of obesity and/or obesity related diseases.

It is to be understood that although much of the following description is generally directed to gastric banding systems of the invention, the present invention is in no way limited thereto. Other embodiments of the invention may be applied to regulate the functioning of other body organs or ducts, such as in the treatment of gastro-esophageal reflux disease, urinary or fecal incontinence, colostomy, or to regulate blood flow.

In this exemplary embodiment, the system 10 generally comprises an implantable portion 12 including an adjustable band 20, an interface 14 including an antenna/controller pod 15, and a control 16 in communication, for example, telemetric communication, with the pod 15. Pod 15 may be connected to the band 20 by means of antenna cable 17 and may include removable tag 18 for facilitating laparoscopic positioning thereof.

Laparoscopically implanted gastric bands and their use in the treatment of obesity are now well known. Generally,

in accordance with the present invention, the band 20 is structured to be implantable in a patient, for example, laparoscopically implantable, around an upper region of the patient's stomach, thereby forming a stoma that restricts food intake and provides feelings of satiety. The inner diameter of the band 20 is adjustable in vivo in order to enable a physician or patient to achieve most desirable stoma size, and the best clinical results.

The band 20 includes a first end 22 and a second end 24, a distal region 26 and a proximal region 28, and a connector 30 configured to couple the first end 22 with the second end 24 of the band 20 such that the band 20 is formable into a loop configuration, as shown.

When the band 20 is formed into said loop configuration, the proximal region 28 forms an inner circumferential surface which at least partially circumscribes and contacts the organ or duct, for example, the stomach, to be regulated or controlled.

Generally, by loosening or tightening the band 20 about the stomach, regulation and/or functioning of the stomach can be controlled or adjusted. When not connected at first and second ends 22, 24, the band 20 can be temporarily straightened in order to facilitate surgical implantation, for example, via laparoscopic techniques.

The system 10 further comprises a contact region 44 disposed between the first and the second ends 22, 24 of the band 20. Turning now to Figs. 2 and 3, the contact region 44 may comprise, at least in part, an elastic component made of, for example, a molded silicone elastonomer. The elastic component comprises a membrane 45 having a generally tubular form which covers or encases the internal mechanisms of the

band 20, for example, gastric band tightening mechanisms such as those to be described hereinafter. The membrane 45, when at rest, may have an arcuate or C-shaped form.

As shown in Fig. 2, contact region 44 comprises first segments 48 and second segments 52 arranged in a generally alternating manner. The first segments 48 may be defined by generally planar and/or convex stomach-facing surfaces, i.e. proximal surfaces, of the contact region 44. The second segments 52 may be defined by generally concave exterior surfaces generally forming indentations between the first segments 48.

In some embodiments, the first segments 48 comprise cushion segments 60. The cushion segments 60 are spaced apart from one another by the second segments 52. The cushion segments 60 may be made of non-compressible material, for example, a silicone elastomer.

In one aspect of the present invention, a suitable incompressible material making up the cushions is a moldable material that has substantially constant density throughout and maintains its volume when deformed. The volume of incompressible materials cannot be reduced more than a nominal amount (e.g., about 5%) when subjected to static compression, or external pressure. The cushions may be a soft silicone material that is a deformable, resilient solid or a gel.

The cushion segments 60 may be made of a material that has a different durometer, for example, is softer, than the material forming the membrane 45. In a specific embodiment, the cushions comprise a soft, molded silicone elastomer material having hardness of 5 Shore A. The membrane

comprises a soft molded silicone elastomer material having a hardness of 30 Shore A.

In one embodiment, cushions 60 may be structured to provide form, definition, support and/or structural integrity to the first segments 48. The second segments 52 may be portions of the membrane 45 which are stretched under tension. The second segments may be structured to provide stability to the contact region 44 and to maintain positioning, for example, circumferential positioning, of the cushions 60 during use of the system 10.

Turning now specifically to Fig. 3, the first segments 48 may have a first axial width W1, and the second segments have a second axial width W2 which is less than the first axial width W1.

In the shown embodiment of the invention, the contact region 44 includes seven first segments 48 (including 48'), each first segment being generally equally spaced apart by intermediate second segments 52. In other embodiments of the invention, contact region 44 includes at least three first segments, at least four first segments, at least five first segments, or at least six first segments. In other embodiments of the invention, the contact region 44 includes more than seven first segments, for example, up to ten first segments or more.

In another aspect of the invention, membrane 45 may be structured to facilitate expansion in a radial direction during adjustment of the inner circumference of the band 20. For example, turning now to Fig. 3, membrane 45 may include radially expandable surfaces 56. For example, membrane 45 includes one or more corrugations 58.

In the shown embodiment, the corrugations 58 are generally aligned with the cushion segments 60. As shown in Fig. 3A, the corrugations 58 may be defined by convolutions 58a defined in an upper surface and lower surface of the membrane 45. The corrugations 58 may be placed to minimize the force required by the actuating mechanism to elongate the membrane 45 in the radial direction. Rather than requiring excessive stretching of the membrane, the membrane unfolds during adjustment.

In the shown embodiment, certain first segments 48 include corrugations 58 and other first segments (e.g. first segments 48') do not include corrugations. For example, intermediate first segments 48 include corrugations 58 and terminal first segments 48' do not include corrugations.

The presently described and shown corrugated structure of the contact region 44 may function to facilitate controlled expansion and/or contraction of the first segments 48, for example, during adjustment of the inner circumference of the band. In some embodiments of the invention, the corrugated surfaces 56 function, at least in part, to decrease the level of force required to adjust the inner circumference of the loop.

In some embodiments, the contact region 44 includes first cushions 60 and second cushions 60a which are configured somewhat differently than first cushions 60. In the shown embodiment, first cushions 60 are located on intermediate first segments 48 and second cushions 60a are located on terminal first segments 48' (i.e. those first segments located at the extremities of the contact region 44).

More specifically, in the embodiment shown in Fig. 2, each first cushion 60 includes a substantially planar or convex face 61 and at least one or more distal projections 62. For example, each cushion 60 includes three longitudinal, arcuate projections 62 as shown. A cross-sectional view of first cushion 60 having these features is also shown in Fig. 3A.

Fig. 4A shows an elevation view of the contact region 44 (cushions not shown) in order to illustrate width W1 of first segment 48 relative to width W2 of second segment 52 of contact region 44. In an exemplary embodiment of the invention, W1 is about 17 mm and W2 is about 13 mm.

Fig. 4B shows an elevation view of an alternative contact region 44' in accordance with the invention. Contact region 44' is identical to contact region 44 shown in Fig. 4A, with a primary difference being that first segment width W1' of contact region 44' is greater than first segment width W1 of contact region 44. That is, W1' > W1. The additional width of first segment width W1' is provided by upper and lower protuberances 66 on first segments 48'. In an exemplary embodiment, W1' is about 19 mm and W2 is about 13 mm. Fig. 4C shows a perspective view of contact region 44' having first segments 48' with protuberances 66.

Turning now to Figs. 5A-5D, an exemplary inner mechanism of the band 20 which enables adjustment of the inner circumference of the loop configuration will now be described. Band 20 may comprise a flexible tension element 132 having fixed end 133 mounted to first end 22 of band 20 and another end 134 that is coupled to an actuator 135 at second end 24 of adjustable element 20. Tension element 132 is slidingly disposed within a substantially cylindrical

tube of axially compressible material 136. When tension element 132 is pulled through actuator 135, compressible material 136 is compressed and the diameter of loop opening 137 is reduced.

Turning now specifically to Figs. 5B through 5D, compressible material 136 may be surrounded on a distal face 137 thereof with a flexible, relatively sturdy elastomeric material, such as silicone element 138. Both compressible material 136 and silicone element 138 are enclosed within the membrane 45 of contact region 44.

In one aspect of the invention, the band 12 may be structured to provide an amplified adjustment feature. This concept is illustrated in Figs. 5E and 5F, and in Figs. 26 thru 27A.

The incompressible cushion segments 60 provide enhanced and more efficient control of adjustment of the inner diameter of the band 20. Figs. 5E and 5F are schematic representations of the cross-section of the band in the open configuration and constricted configuration, respectively. Outer diameter D represents the outer diameter of axially adjustable portion of the band 20. Areas of individual cushion regions 60 are represented by areas A_I in Fig. 5E (open configuration). The total area occupied by the individual cushion regions is represented as annular area A_T in Fig. 5F (constricted configuration). Surface S represents the available lumen around the stomach (or other organ or duct being controlled or regulated) and diameter Deq represents an equivalent diameter, that is, the diameter of a circle having the same surface area as S.

When the loop is constricted from the fully open state, diameter D (Fig. 5E) becomes D' (Fig. 5F), the surface S

becomes S' and the equivalent diameter Deq becomes D'eq. Because the cushions occupying A_I are incompressible, the total surface area A_T occupied by the cushions does not change. The equivalent diameter Deq decreases more rapidly than the diameter D.

For example, D=29mm in a fully open position and a total surface of the incompressible cushions A_T equal to about 120 square mm: S=540.52 sq mm and Deq=26.2mm. When in fully closed position, D'=19mm: S'=163.53 sq mm, and D'eq=14.4. Thus D-D'=10mm, and Deq-D'eq=11.8mm, which provides an "amplification factor" of about 1.18. Thus, by changing the values of D, D' and A_T, the amplification factor can be controlled.

The substantially incompressible cushion segments allow a relative restriction of the lumen during adjustment greater than without substantially incompressible cushion segments. That greater relative restriction arises from the fact that the cross-section of the substantially incompressible cushion segments remains constant during adjustment, whereas the area of the lumen decreases during closure, so that the ratio (cushion cross-section)/(lumen) increases. Accordingly, the substantially incompressible cushion segment effect on lumen restriction increases during closure.

Figs. 5G and 5H show a simplified schematic representation an embodiment of the invention in which contact region 444 comprises an elastic membrane 445 and a single continuous, incompressible cushion segment 460 instead of the individual, separate cushion segments 60 shown in Fig. 2. Other than cushion segment 460 being a single substantially continuous cushion segment rather than a plurality of individual separate cushion segments 60, the

band 420 may be identical to band 20. The continuous cushion segment 460 is configured or shaped to accommodate tension segments 452 of the membrane 445. For example, the continuous cushion segment 460 has a variable thickness, with the thickest regions functioning similarly to incompressible cushion regions 60 described elsewhere herein. Fig. 5H shows bending of tension regions 452 and deformation of incompressible cushions 60 during the constriction of the loop.

Turning back to Fig. 5A, band 20 may further comprise member 140 of a relatively rigid material. By its structural rigidity, member 140 imposes a generally circular arc shape for the entirety of band 20. In some embodiments of the invention, rigidity of band 140 functions to prevent the exterior diameter of band 12 from changing during adjustment of the internal diameter of the loop.

Generally, an increase or reduction of the length of tension element 132 results in reversible radial displacement at the internal periphery of the band 20. This in turn translates into a variation of internal diameter of the loop from a fully open diameter to a fully closed diameter.

In various embodiments of the invention, the diameter of the opening 137 formed by the band 20 may be between about 25 mm or about 35 mm in a fully dilated position (e.g. see Fig. 5C). The diameter of the opening 137 may be between about 15 mm and about 20 mm when the band 20 is in a fully constricted position (e.g. see Fig. 5D).

Figs. 6A, 6B and 6C show the band 12 at progressively increased levels of constriction, with Fig. 6A showing the opening 137 being larger than in Fig. 6B, which shows the

opening 137 larger than in Fig. 6C. In the shown embodiment of the invention, while diameter of opening 137 is adjustable, the diameter an outer circumferential surface 139 of the band 12 remains relatively fixed during adjustments of the opening 137. Membrane 45 of contact region 44 stretches or unfolds as described elsewhere herein, as axially compressible material 136 moves apart from distal element 130 and band (not visible in Figs 6A-6C) and opening 137 constricts. (See also Fig. 5D).

Referring now to FIG. 7, tension element 132 is described. In some embodiments, tension element 132 has sufficient flexibility to permit it to be formed into a substantially circular shape, while also being able to transmit the force necessary to adjust the inner diameter of the loop. Tension element 132 may comprise flexible core 141, for example, comprising a metal alloy wire of circular cross section, on which is fixed, and wound coaxially, at least one un-joined coil spring which defines a screw thread pitch.

Tension element 32 may comprise two un-joined coil springs that form a screw thread: first spring 142, wound helicoidally along the flexible core 141, and second spring 143 of greater exterior diameter. Second spring 143 preferably comprises coils 144 of rectangular transverse section, so as to delineate a flat external generatrix. First spring 142 is interposed between coils 144 of the second spring 143 to define and maintain a substantially constant square screw thread pitch, even when the tension element is subjected to bending.

Second spring 143 may be made by laser cutting a cylindrical hollow tube, e.g., made from stainless steel, or alternatively, by winding a wire with a rectangular,

trapezoidal or other cross-section. When helically intertwined with first spring 142, coils 144 of second spring 143 are activated with an intrinsic elastic compression force from the adjacent coils of first spring 142. First spring 142 is intertwined between the coils of second spring 143. First spring 142 is fixedly joined to flexible core 141 at one end. At the second end, a crimped cap 145 (see FIG. 8) is located a short distance from the ends of springs 142 and 143 to allow for small extensions, for example, to accommodate flexion of tension element 132 and/or to limit this extension to keep the thread pitch substantially constant.

Referring now to FIG. 8, free end 134 of tension element 132 includes crimped cap 145. Second spring 143 includes coils having a square transverse section. Flexible core 141 extends through first and second springs 142 and 143, and terminates close to cap 145. In one embodiment of the invention, tension element 132 further comprises third spring 146 that is coupled to flexible core 141, and first and second springs 142 and 143 at junction 147. Third spring 146 includes loop 148 at the end opposite to junction 147, which permits the tension element 132 to be fixed at first end 22 of band 20.

With respect to Fig. 9, tension element 132 is shown disposed within a skeleton 150 of the band 20. Skeleton 150 includes layer 151 that forms a distal periphery, anchor 152 that accepts loop 148 of tension element 132, and actuator housing 153. Skeleton 150 may be made of a high strength moldable plastic.

In accordance with another aspect of the invention, third spring 146 permits band 12 to be straightened for insertion through a trocar, for example a 18 mm trocar,

despite a differential elongation of the skeleton 150 and tension element 132. This feature is illustrated in FIG. 10 which shows band 12 disposed in a trocar 300 in order to facilitate laparoscopic implantation of the band 12.

Referring now to FIG. 11, in the shown embodiment, connector 30 includes housing 155 having recessed portion 156, tension element cavity 157 and cable lumen 158. Recess 156 is configured to accept actuator housing 153 of skeleton 150, so that as tension element 132 is drawn through actuator 135 it extends into tension element cavity 157. Cable lumen 158 extends through housing 155 so that cable 124 may be coupled to actuator 135. Housing 155 may be grasped in area G using atraumatic laparoscopic graspers during implantation.

In FIG. 12, actuator housing 153 of skeleton 150 is shown with actuator 135 and tension element 132 disposed therethrough. Antenna cable 17 is coupled to motor (not shown) disposed within actuator housing 153. Tension element 132 is in the fully opened (largest diameter) position, so that crimped cap 145 contacts printed circuit board 159 of the reference position switch described below with respect to FIG. 15.

With respect to FIGS. 13 and 14, actuator 135 includes motor 166 coupled to antenna cable 17 that drives nut 160 through gears 161. Nut 160 is supported by upper and lower bearings 162 to minimize energy losses due to friction. Nut 160 is self-centering, self-guiding and provides high torque-to-axial force transfer. In addition, nut 160 is self-blocking, meaning that nut 160 will not rotate due to the application of pushing or pulling forces on tension element 132. This condition may be achieved by ensuring that the height (h) of the thread divided by the circumference of

the screw ($2\pi R$) is less than the arctangent of the friction coefficient (p):

$$h/(2\pi R) < \arctan(\mu)$$

Gears 161 preferably are selected to provide good mechanical efficiency, for example, with a reduction factor greater than 1000. In addition, the volume of the actuator depicted in FIGS. 13 and 14 may be quite small, with a total volume less than 1 cm^3 and a diameter less than 12.5 mm, so that the device may easily pass through a standard trocar. In a preferred embodiment, gears 161 are selected to provide a force of more than 2 kg on the screw thread of the tension element at an electrical consumption of only 50 mW. The gears and other components of actuator 135 may be made of stainless steel or other alloys like Arcap (CuNiZn), or can be gold plated to permit operation in the high humidity likely to be encountered in a human body.

Motor 166 employed in actuator 135 may comprise a Lavet-type high precision stepper motor with a flat magnetic circuit, such as are used in watches. The motor 166 may be a two phase (two coil) motor that permits bi-directional rotation, has good efficiency, and may be supplied with a square wave signal directly by the microcontroller circuitry within antenna/controller pod 15, thus eliminating the need for an interface circuit. Alternatively, the motor employed in actuator 135 may be of a brushless DC type motor. In addition, the motor preferably is compatible with magnetic resonance imaging, i.e., remains functional when exposed to strong magnetic fields used in medical imaging equipment.

Referring now to FIG. 15, a reference position switch of an embodiment of the present invention is described. In one embodiment the actuator of the present invention employs

nut 160 driven by a stepper motor. Thus, there is no need for the system to include a position sensor or encoder to determine the length of tension element 132 drawn through the actuator. Instead, the diameter of opening 137 may be computed as a function of the screw thread pitch and the number of rotations of nut 160. At least one reference datum point may be provided which may be calculated by using a reference position switch that is activated when band 12 is moved to its fully open position. Crimped cap 145 on the free end of tension element 132 may be used to serve this function by contacting electrical traces 163 on printed circuit board 159 (and also limits elongation of the screw thread). Circuit board 159 is disposed just above bearing 165, which forms part of actuator 135. When crimped cap 145 contacts traces 163 it closes a switch that signals the implantable controller that the band 12 is in the fully open position.

Referring now to Figs. 16A and 16B, clip 30 may include a clip element 167 on first end 22 of band 20 and the housing 155 on the second end of the band 20. Clip element 167 includes aperture 170, tab 171 having hinge 172 and slot 173. Aperture 170 is dimensioned to accept housing 155 on second end 24 of band 20, while slot 173 is dimensioned to accept flange 174 disposed on second end 24.

An example of a method of coupling the first end 22 with second end 24 during implantation of the band 20 is now described. To couple first end 22 and second end 24, clip element 167 is grasped by the tab 171, and tag 18 of pod 15 (see Fig. 1) is inserted through aperture 170. Clip element 167 is then pulled towards second end 24 so that housing 155 passes through aperture 170 while housing 155 is grasped with atraumatic forceps; the conical shape of housing 155 facilitates this action. Force is applied to tab 171 until

slot 173 captures flange 174, thereby securing the first and second ends 22, 24 in the closed position. The physician may subsequently choose to disengage slot 173 from flange 174 by manipulating tab 171 using laparoscopic forceps, for example, to reposition the band 12. In some embodiments, forces inadvertently applied to tab 171 in an opposite direction will cause tab 171 to buckle at hinge 172, but will not cause flange 174 to exit slot 173. Accordingly, hinge 172 of tab 171 prevents accidental opening of clip 30 when the tab 171 is subjected to forces that cause the tab 171 to fold backwards away from housing 155 such as may arise due to movement of the patient, the organ, or bolus of fluid passing through the organ.

With respect to Figs. 17 and 18, removable tag 18 of antenna/controller pod 15 may include apertures 175. Tag 18 comprises a grip structure that facilitates manipulation and placement of the pod during implantation; after which the tag is removed, for example, using a scissors cut. Tag 18 also includes aperture 18b that allows the use of a suture thread to assist in passing the antenna/controller pod 15 behind the stomach. Holes 175 also are dimensioned to be compatible with standard suture needles from size 1-0 to 7-0 to permit pod 15 to be sutured to the patient's sternum, thereby ensuring that pod 15 remains accessible to the external antenna and cannot migrate from a desired implantation site.

As shown in FIG. 18, antenna/controller pod 15 encloses printed circuit board 176 that carries the antenna and microcontroller circuitry of band (not shown). The antenna receives energy and commands from external control 16 (see Fig. 1), and supplies those signals to the microcontroller, which in turn powers motor 166 of actuator 135 (Figs 12 and 13). The circuitry of antenna/controller pod 15 uses the

energy received from the incoming signal to power the circuit, interprets the commands received from external control 16, and supplies appropriate signals to the motor of actuator 135. The circuit also retrieves information regarding operation of the motor 166 of actuator 135 and relays that information to external control 16 via the antenna. The circuit board 176 may be covered with a water-resistant polymeric covering, e.g., Parylene, to permit use in the high (up to 100%) humidity environment encountered in the body.

Antenna/controller pod 15 may include a mechanical closure system that is augmented by silicone glue so that the pod 15 is fluid tight. This silicone glue also is used to protect soldered wires.

Actuator 135 may be linked to subcutaneous antenna/controller pod 15 to receive a radio frequency control and power signal. In one embodiment, the motor 166 of the actuator 135 has no internal energy supply, but rather is powered by the receiving circuit of the antenna through a rechargeable energy storage device, such as a capacitor. For example, the receiving circuit converts radio frequency waves received from external control 16 via the antenna into a motor control and power signal. In another embodiment the actuator 135 may be driven via an implantable rechargeable battery.

Referring to Fig. 19, one suitable arrangement of circuitry that may be employed in external control 16 of the present invention is described. External control 16 includes microprocessor 180 coupled to a keyboard/control panel 212 and display 213. External control 16 produces a signal comprising one or more data bytes to be transmitted

to the implantable antenna/controller pod (not shown) and actuator 135.

External control 16 includes modulator 181 for amplitude modulation of the RF wave from RF generator 182, which signal is emitted by an external antenna 214. The emitted wave is received by antenna 183 in the antenna/controller pod (not shown), where AM demodulator 184 extracts the data bytes from the envelope of received RF signal. The data bytes then are decoded by microcontroller 185. A special code is used that allows easy decoding of the data by microcontroller 185, but also provides maximal security against communication failure.

External oscillator 186, which is a voltage controlled oscillator (VCO), provides a clock signal to microcontroller 185. Oscillator 186 may comprise, for example, a relaxation oscillator comprising an external resistor-capacitor network connected to a discharging logic circuitry already implemented in the microcontroller or a crystal oscillator comprising a resonant circuit with a crystal, capacitors and logic circuits.

Microcontroller 185 interprets the received instructions and produces an output that drives the motor of actuator 135. As discussed above, actuator 135 may comprise a bi-directional stepper motor that drives nut 160 through a series of reducing gears. In one embodiment, the two coils of the stepper motor of actuator 135 are directly connected to microcontroller 185, which receives the working instructions from demodulator 184, interprets them and provides the voltage sequences to the motor coils. When the supply of voltage pulses to the stepper motor stops, the gears are designed to remain stationary, even if a reverse

torque or force is applied to nut 160 by tension element 132.

As also described above, use of a stepper motor in actuator 135 makes it is possible to obtain positional information on nut 160 and tension element 132 without the use of sensors or encoders, because the displacement of the tension element is proportional to the number of pulses supplied to the stepper motor coils. Two signals may be employed to ensure precise control, reference position signal S_{RP}, generated by the reference position switch of FIG. 15, and the actuator signal S_A.

According to one embodiment, signal S_A is the voltage signal taken at one of the outputs of microcontroller 185 that is connected to the motor coils of actuator 135. Alternatively, signal S_A could be derived from the current applied to a motor coil instead of the voltage, or may be an induced voltage on a secondary coil wrapped around one of the motor coils of actuator 135. In either case, signal S_A may be a pulsating signal that contains information on the number of steps turned by the rotor and further indicates whether blockage of the mechanism has occurred. Specifically, if the rotor of the stepper motor fails to turn, the magnetic circuit is disturbed, and by induction, affects signal S_A, e.g., by altering the shape of the signal. This disturbance can be detected in the external control, as described below.

Signals S_A and S_{RP} are converted into frequencies using external oscillator 186, so that the voltage level of signal S_A applied to external oscillator 186 causes the oscillator to vary its frequency F_{OSC} proportionally to the signal S_A. Thus, F_{osc} contains all the information of signal S_A. When crimped cap 145 and tension element 132 are in the reference

position (band 12 is fully open), the reference position switch produces reference position signal S_{RP}. Signal S_{RP} is used to induce a constant shift of the frequency F_{OSC}, which shift is easily distinguishable from the variations due to signal S_A.

If oscillator 186 is a relaxation oscillator, as described above, signals S_A and S_{RP} modify the charging current of the external resistor capacitor network. In this case, the relaxation oscillator may comprise an external resistor-capacitor network connected to a transistor and a logic circuit implemented in microcontroller 185. With S_A and S_{RP}, the goal is to modify the charging current of the capacitor of the RC network to change the frequency of the relaxation oscillator. If the charging current is low, the voltage of the capacitor increases slowly and when the threshold of the transistor is reached, the capacitor discharges through the transistor. The frequency of the charging-discharging sequence depends on the charging current.

If oscillator 186 is a crystal oscillator, signals S_A and S_{RP} modify the capacitor of the resonant circuit. In this case, the crystal oscillator circuit preferably comprises a crystal in parallel with capacitors, so that the crystal and capacitors form a resonant circuit which oscillates at a fixed frequency. This frequency can be adjusted by changing the capacitors. If one of these capacitors is a Varicap (a type of diode), it is possible to vary its capacitance value by modifying the reverse voltage applied on it, S_A and S_{RP} can be used to modify this voltage.

In either of the foregoing cases, signals S_A and S_{RP} may be used to modify at least one parameter of a resistor-capacitor (RC) network associated with the oscillator 186 or

at least one parameter of a crystal oscillator comprising the oscillator 186.

Referring still to FIG. 19, signals S_A and S_{RP}, derived from the stepper motor or from the output of the microcontroller 185, may be used directly for frequency modulation by the oscillator 186 without any encoding or intervention by the microcontroller 185. By using oscillator 186 of microcontroller 185 as part of the VCO for the feedback signal, no additional components are required, and operation of micro controller 185 is not adversely affected by the changes in the oscillator frequency F_{osc}. The oscillating signal F_{osc} drives voltage driven switch 187 for absorption modulation, such that feedback transmission is performed with passive telemetry by FM-AM absorption modulation.

More specifically, signal F_{osc} drives switch 187 such that during the ON state of the switch 187 there is an increase in energy absorption by RF-DC converter 188. Accordingly, therefore the absorption rate is modulated at the frequency F_{osc} and thus the frequency of the amplitude modulation of the reflected wave detected by external control 16 contains the information for signal S_A. As discussed below, pickup 189 in external control 16 separates the reflected wave where it can be decoded by FM demodulation in demodulator 190 to obtain signal $S_{A'}$. This method therefore allows the transmission of different signals carried at different frequencies, and has the advantage that the ON state of switch 187 can be very short and the absorption very strong without inducing an increase in average consumption. In this way, feedback transmission is less sensitive to variation in the quality of coupling between the antennas 183 and 214.

In external control 16, the feedback signal F_{OSC} is detected by the pickup 189 and fed to FM demodulator 190, which produces a voltage output V_{OUT} that is proportional to F_{OSC}. V_{OUT} is fed to filter 191 and level detector 192 to obtain the information corresponding to the actuator signal S_A, which in turn corresponds to the pulses applied to the stepper motor coil. Microprocessor 180 counts these pulses to calculate the corresponding displacement of the tension element 32, which is proportional to the number of pulses.

Signal V_{OUT} also is passed through analog-to-digital converter 193 and the digital output is fed to the microprocessor 180, where signal processing is performed to detect perturbations of the shape of the feedback signal that would indicate a blockage of the rotor of the stepper motor. Microprocessor 180 stops counting any detected motor pulses when it detects that the actuator is blocked, and outputs an indication of this status. Level detector 194 produces an output when it detects that the demodulated signal V_{OUT} indicates the presence of the reference position signal S_{RP} due to activation of the reference position switch. This output induces a reset of the position of the tension element calculated by microprocessor 180 in the external control. In this way, a small imprecision, e.g. an offset, can be corrected.

As described above, external control 16 may be configured to transmit both energy and commands to the implantable controller circuitry in antenna/controller pod 15. External control 16 may also receive feedback information from the implantable controller that can be correlated to the position of the tension element and the diameter of the loop. As will be apparent to one of skill in the art, external control 16 and the implantable controller may be configured in a master-slave arrangement, in which

the implantable controller is completely passive, awaiting both instructions and power from external control 16.

Power may be delivered to the implantable pod 15 via magnetic induction. The quality of the coupling may be evaluated by analyzing the level of the feedback signal received by external control 16, and a metric corresponding to this parameter may be displayed on signal strength indicator 217 on control 16, which in the shown embodiment, includes 6 LEDs (corresponding to six levels of coupling). If the coupling between the antennae is insufficient, the motor of actuator may not work properly.

Referring now to FIG. 21, band 20 of the presently described system of the invention is shown implanted in a patient. Band 20 of band 12 is disposed encircling the upper portion of the patient's stomach S while antenna/controller pod 15 is disposed adjacent to the patient's sternum ST. Pod 15 is located in this position beneath the patient's skin SK so that it is easily accessible in the patient's chest area to facilitate coupling of the implanted pod 15 to an external antenna of control 16.

Referring to FIGS. 22A to 22H, a method of implanting the band and pod of the system of the present invention is described. The method is similar to laparoscopic procedures used to implant previously-known hydraulically-actuated gastric bands.

Access to the abdomen is obtained by using 4 to 6 small holes, generally 10 to 18 mm in diameter, with a trocar inserted in each hole, as depicted in FIG. 22A. A camera and laparoscopic surgical tools are introduced and manipulated through the trocars. In addition, to permit free

motion of the surgical tools and camera, the abdomen is inflated with CO_2 to an overpressure of approximately 0.15 bars.

In Figs. 22B-22E, the band 20 of the adjustable portion 12 is straightened (as depicted in FIG. 10) and inserted, antenna first, into the abdomen through an 18 mm trocar. Alternatively, a laparoscopic cannula may be used to make an incision and then withdrawn, and the device inserted through the opening so created (other instruments also may be used to form this laparotomy). In Fig. 22B, tag 18 of antenna/controller pod 15 is shown entering the abdomen through trocar 300 using atraumatic graspers 310. In Fig. 22C, housing 155 is shown being drawn into the abdomen through trocar 300, again using atraumatic graspers 310. Fig. 22D shows band 20 entering the abdomen in an extended position. In Fig. 22E, the band 20 is permitted to resume its arcuate shape.

Band 20 then is manipulated using atraumatic graspers 310 as described elsewhere herein, to secure the band 20 around the upper portion of the patient's stomach until slot 173 of clip 30 is engaged with flange 174, as shown in Fig. 22F. A fold of stomach tissue then may be sutured around the band 20 to prevent migration of the band 20.

Finally, as shown in Fig. 22G, a channel may be formed through the abdominal wall and antenna/controller pod 15 passed through the channel. Tag 18 then is cut off of antenna/controller pod 15, and the pod 15 is sutured into position above the patient's sternum, as depicted in Fig. 22H. The trocars then are removed, and the band 20 may be activated to adjust the diameter of the inner diameter as desired by the physician.

The process of removing the band 20 of the present invention involves substantially reversing the sequence of steps described above, and may be accomplished non-destructively. In particular, a plurality of cannulae into the abdominal cavity and the abdominal cavity then insufflated to create a pneumoperitoneum. Using laparoscopic graspers, the clip 30 may be unclipped and the band 20 removed from a position encircling the patient's stomach. The band 20 may then be straightened and withdrawn from the abdominal cavity either through one of the plurality of cannulae or via a laparotomy.

Figs. 23 through 25 illustrate an alternative contact region 1010 of a gastric banding system of the present invention. Contact region 1010 may be identical to contact region 44 except as explicitly described below. Contact region 1010 can replace contact region 44 described and shown, for example, in Figs. 3 and 3A, in system 10.

Contact region 1010 comprises a membrane 1014 which may be substantially identical to membrane 45 described and shown elsewhere herein. In this embodiment however, cushion segments 1016, which may be made of the same incompressible materials as cushion segments 60, are affixed to an external surface of the membrane 1014 and define at least a portion of the stomach-facing surface of the contact region 1010. The cushion segments 1016 may be individually molded to, or molded as a whole, directly to the membrane 1014 using conventional molding techniques, for example, conventional overmolding techniques.

In a specific embodiment, cushions 1016 are made of silicone elastomer having a hardness of 10 Shore A and membrane 1014 is made of silicone elastomer having a hardness of 30 Shore A.

Alternatively, the membrane 1014 may be made of silicone elastomer of different hardness, such as, for example, 20 Shore A to 45 Shore A. Alternatively still, the cushions could be made of an even softer silicone elastomer, such as 5 Shore A or 1 Shore A. Alternatively, the cushions or the membrane could be made of other suitable implantable materials.

Figs. 24 and 25 are cross sectional views of the contact region shown in Fig. 23 taken along line 24-24 and line 25-25, respectively.

Another feature of this embodiment of the invention is shown in Fig 24. Specifically, the membrane 1014 may includes a structural support, for example, a wedge 1025 located at the interface between the membrane 1014 and each of the cushion segments 1016. Wedges 1025 may provide an increased surface area on which the cushion segments are molded thereby providing additional adherence and/or support between the membrane 1014 and the cushion segments 1016. Like membrane 45, membrane 1014 includes corrugations 1027 for facilitating unfolding or expansion of the membrane 1014 during adjustment of the band.

Another advantageous feature of this embodiment is shown in Figs. 26-27A. In some embodiments, the cushion segments 60 and tension segments 52 form an inner circumference of the loop configuration having a generally star-shape, defined by the contact region, as shown in Fig. 26. The stomach lumen is indicated by numeral 1033. During constriction of the band, which is shown dilated in Figs. 26 and 26A and constricted in Figs 27 and 27A, adjacent incompressible cushion segments 60 form, a progressively narrowing angle, for example, a progressively narrowing

substantially V-shaped surface having convex, arcuate surfaces defined by the cushion segments 60. Tension segments 52 located between the adjacent cushion segments 60 and form the vertices of the angles.

While not wishing to be bound by any particular theory of operation, it is believed that the structure of the contact member 44 and at least partially due to the incompressibility of the cushion segments 60 enables the band to constrict about the stomach without pinching the tissue. For example, as shown in Fig 27 and 27A, the stomach tissue does not become entrapped between adjacent cushion segments 60. During constriction of the band, the convex stomach-facing surfaces maintain their shape and form no gaps, while folding inwardly toward one another. This mechanism and structure causes the tissues of the stomach constricted without the tissues becoming entrapped and/or pinched. This progressive V-shape acts differently than a mechanical pliers.

As stated elsewhere herein, the system of the present invention has numerous applications apart from gastric banding. For example, the system of the present invention may be used for the treatment of fecal incontinence, ileostomy, coleostomy, gastro-esophageal reflux disease, urinary incontinence and isolated-organ perfusion.

For treatment of fecal incontinence, the ring may be used with little or no modifications. In addition, because the ring adjustment procedure will be performed by the patient on at least a daily basis, a portable user-friendly external control may be used. In addition, because the ring will regularly be transitioned between the closed and fully opened position, the patient microchip card is unneeded. Instead, the fully closed position may be stored in the

memory of the implantable controller, and read by the external remote at each use (subject to periodic change by the physician).

A similarly modified device could be used by patients who have undergone ileostomy or coleostomy, or disposed surrounding the esophageal junction, to treat gastro-esophageal reflux disease.

For treatment of urinary incontinence, the system of the present invention may be further modified to minimize the volume of the loop surrounding the urethra by moving the actuator motor to a location elsewhere in the lower abdomen or pelvis, and coupling the actuator to the motor via a transmission cable.

The present invention also may be beneficially employed to perform isolated-organ perfusion. The treatment of certain cancers requires exposure to levels of chemotherapy agents that are too high for systemic circulation. It has been suggested that one solution to this problem is perform an open surgery procedure in which blood flow to the cancerous organ is stopped and quiescent blood replaced by circulation from an external source containing a desired dose of drug. Individual or multiple rings of the present invention may be used as valves to isolate the cancerous organ and permit perfusion of the organ with high doses of drugs. Such procedures could thus be performed on a repetitive basis without surgery, thereby reducing the trauma and the risk to the patient while improving patient outcomes.

Although particular embodiments of the present invention have been described above in detail, it will be understood that this description is merely for purposes of

illustration. Further variations will be apparent to one skilled in the art in light of this disclosure and are intended to fall within the scope of the appended claims.

What is claimed is:

1. A system for regulating an organ or duct, comprising:

a band having a first end, a second end, a distal region and a proximal region and a connector configured to couple the first end with the second end such that the band is formable into a loop configuration structured to circumscribe an organ or duct;

a membrane disposed between the first end and the second end of the band;

at least one cushion segment coupled to the membrane and disposed on the proximal region of the band; and

a mechanism for enabling adjustment of an inner circumference of the loop configuration.

2. The system of claim 1 wherein the at least one cushion segment comprises a plurality of cushion segments disposed on the proximal region.

3. The system of claim 2 further wherein the membrane defines a plurality of tension segments disposed in a substantially alternating manner between adjacent cushion segments.

4. The system of claim 1 wherein the at least one cushion segment is made of a substantially incompressible material.

5. The system of claim 1 wherein the at least one cushion segment is made of an incompressible material.

6. The system of claim 1 wherein the at least one cushion segment comprises a single incompressible cushion segment disposed along substantially the entire proximal region.

7. The system of claim 6 wherein the substantially continuous cushion segment includes thick regions and relatively thin regions disposed in a substantially alternating manner between the thick regions.

8. The system of claim 1 wherein the at least one cushion member is located on an external surface of the membrane.

9. The system of claim 1 wherein the at least one cushion segment is molded to the membrane.

10. The system of claim 1 wherein the at least one cushion segment is molded to an external surface of the membrane.

11. The system of claim 1 wherein the at least one cushion segment defines at least a portion of the inner circumferential surface of the band when the band is in the loop configuration.

12. The system of claim 1 wherein the at least one cushion segment is substantially incompressible.

13. The system of claim 1 wherein the membrane includes at least one support wedge secured to the at least one cushion segment.

14. The system of claim 1 wherein the membrane includes corrugated surfaces to allow unfolding of the membrane during adjustment.

15. The system of claim 1 wherein the membrane is made of a first material and the at least one cushion segment is made of a second material having a different durometer than the first material.

16. The system of claim 1 wherein the at least one cushion segment is located on an internal surface of the membrane.

17. The system of claim 1 wherein the mechanism comprises an interface connected to the band, and a control capable of communicating with the interface to regulate constriction of the band about said organ or duct.

18. A system for regulating an organ or duct, comprising:

a band having a first end, a second end, a distal region and a proximal region and a connector configured to couple the first end with the second end such that the band is formable into a loop configuration structured to circumscribe an organ or duct;

a contact region disposed between the first end and the second end of the band;

the inner circumference of the loop configuration having a generally star-shape defined by the contact region; and

a mechanism for enabling adjustment of the inner circumference of the loop configuration.

19. The system of claim 18 wherein the contact region includes a plurality of cushion segments spaced apart by a plurality of tension segments.

20. The system of claim 19 wherein the plurality of tension segments define vertices of the generally star-shape.

21. The system of claim 18 wherein the contact region is structured to prevent pinching of the organ when the band is positioned around the organ and the inner circumference is adjusted.

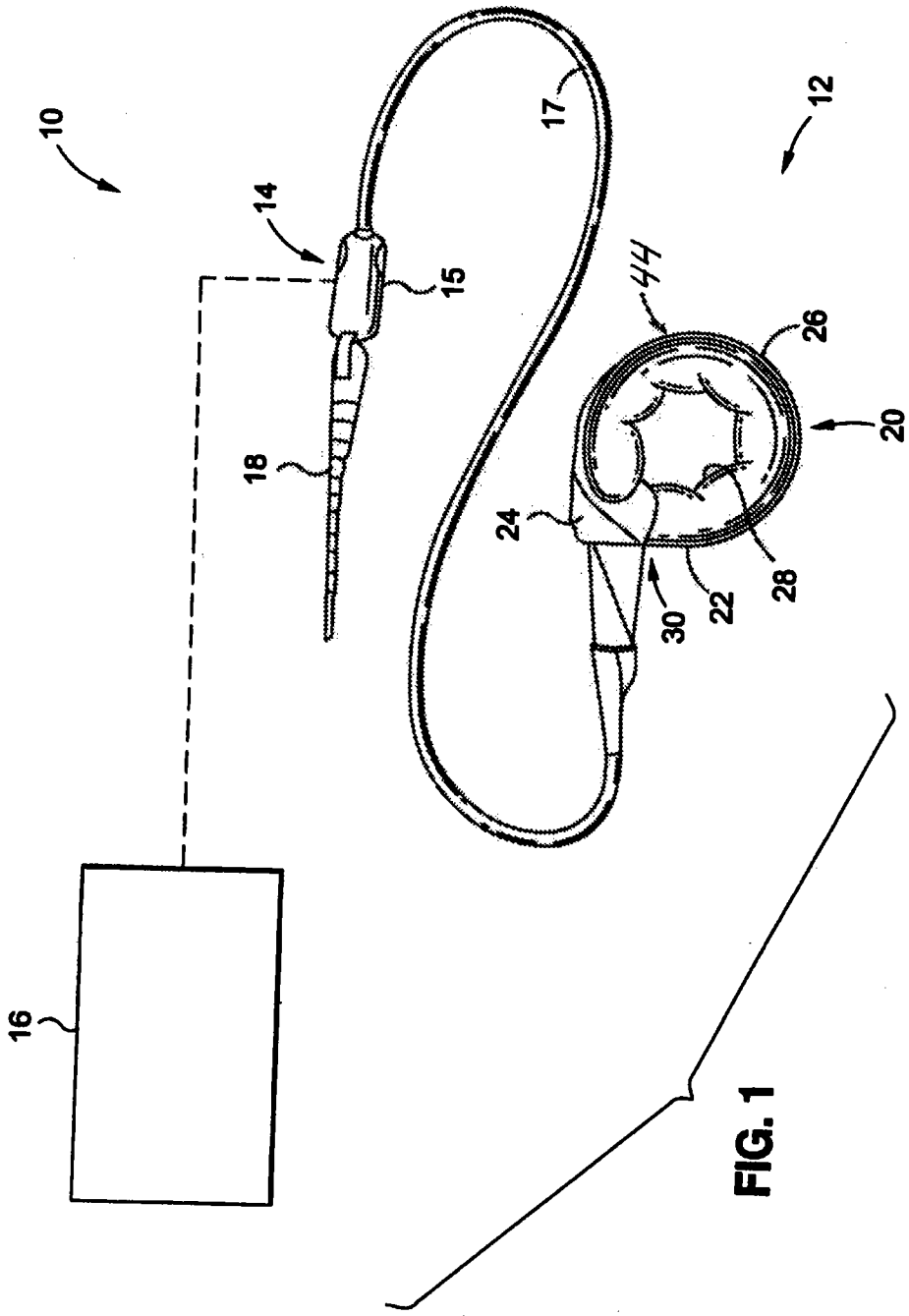


FIG. 1

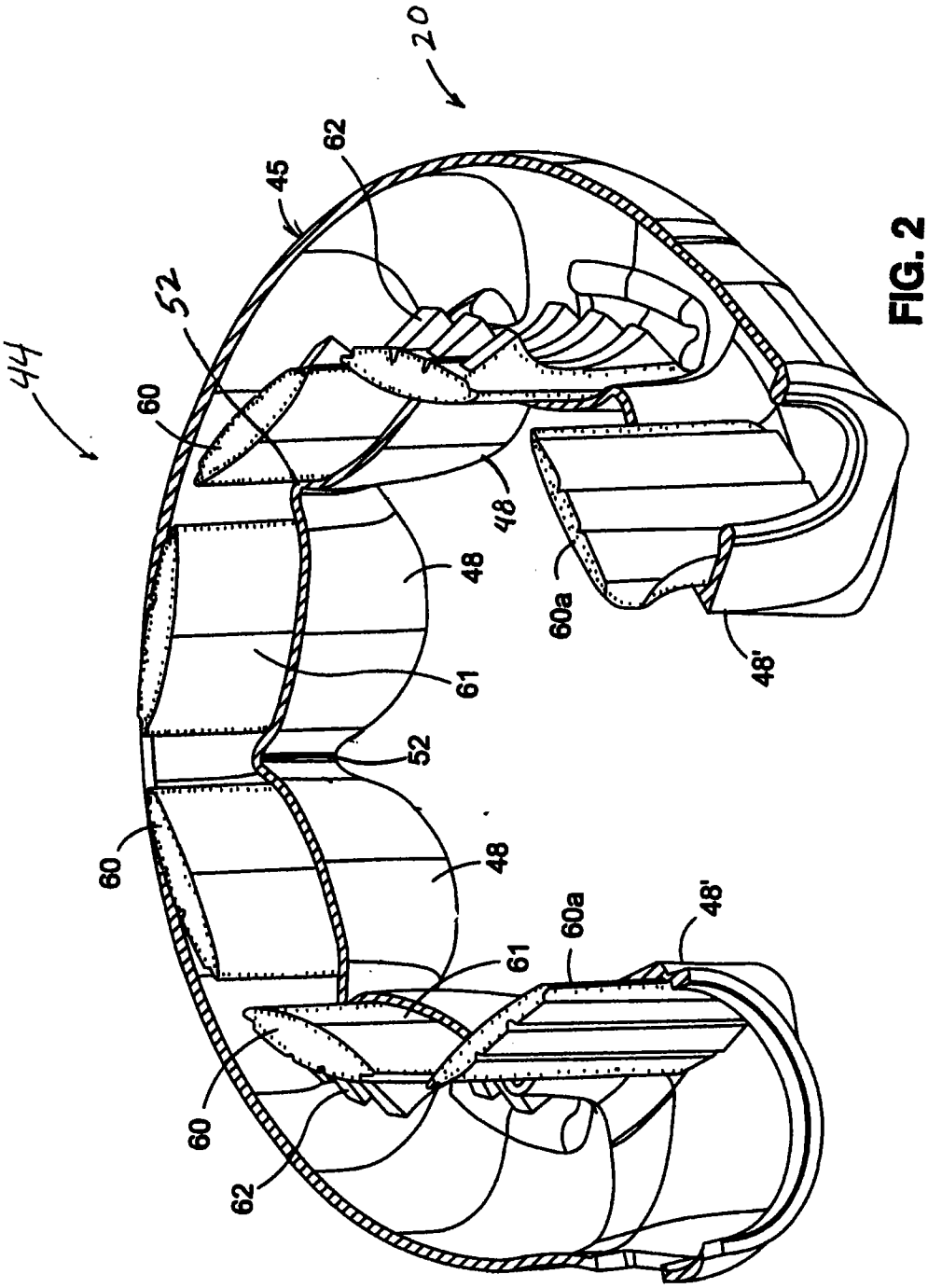


FIG. 2

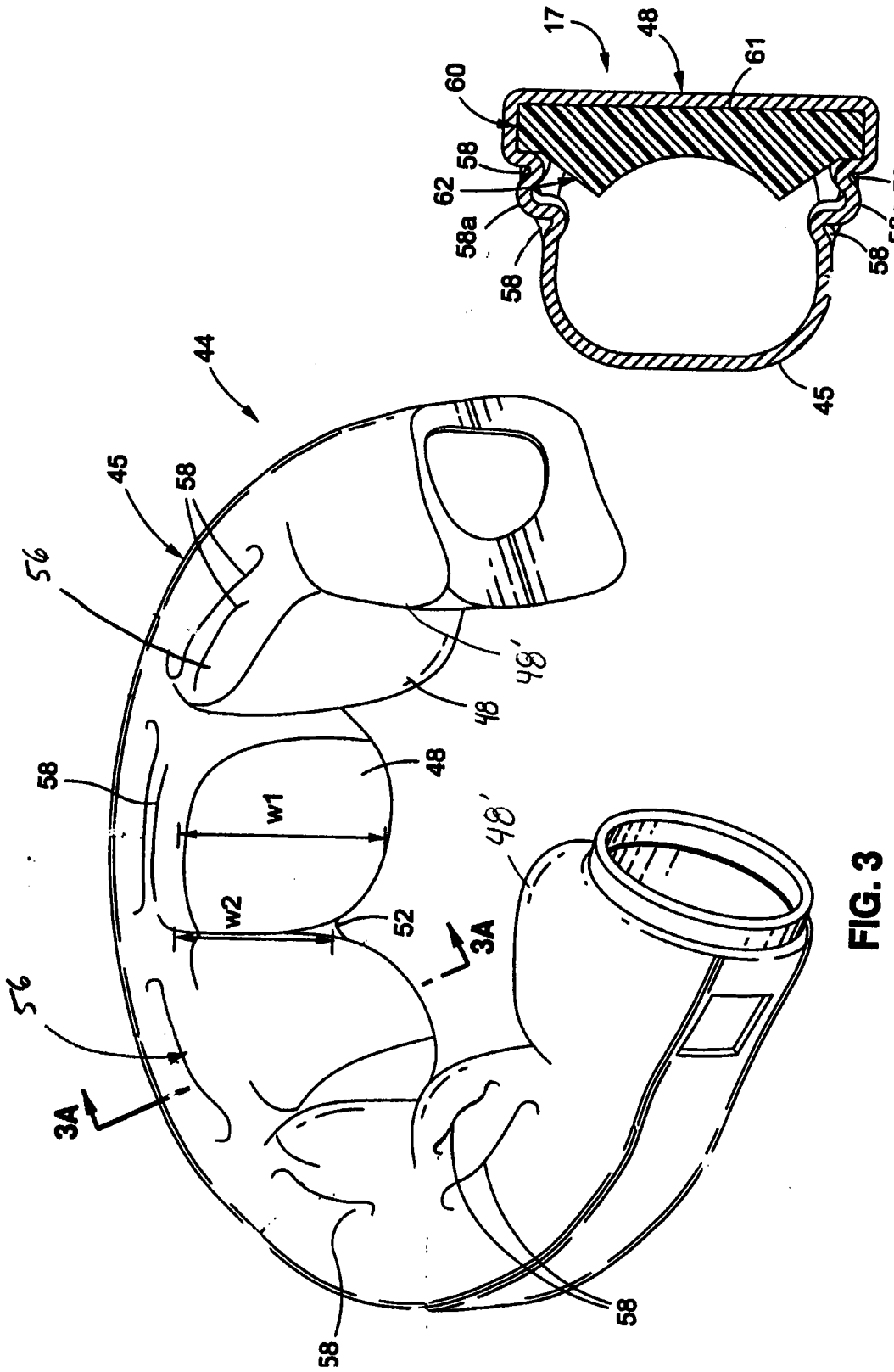

17
48
61
60
58
62
58a
58
58
58a
58
58
45
44
45
58
56
48'
48
58
48
w1
w2
52
48'
3A
3A
56
58
58
58

FIG. 3A

FIG. 3

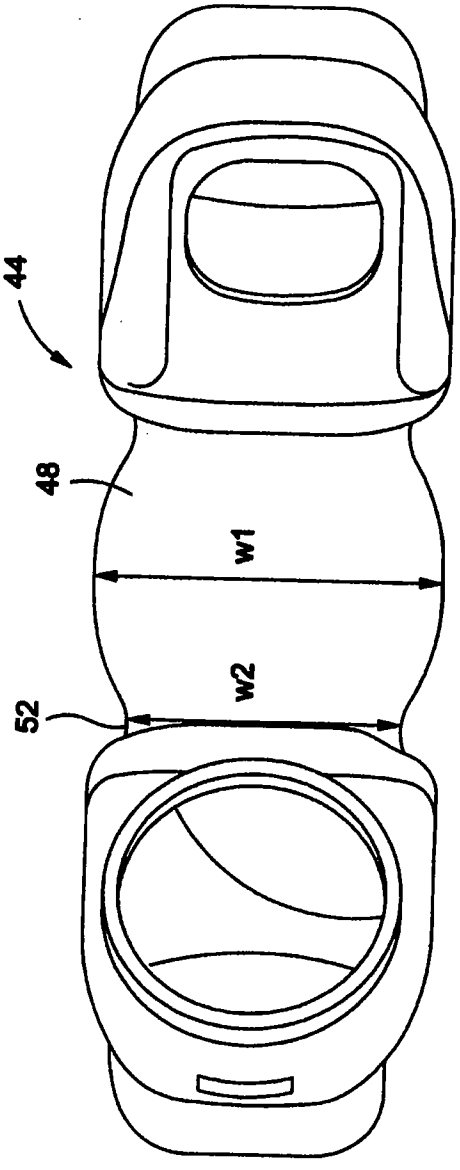


FIG. 4A

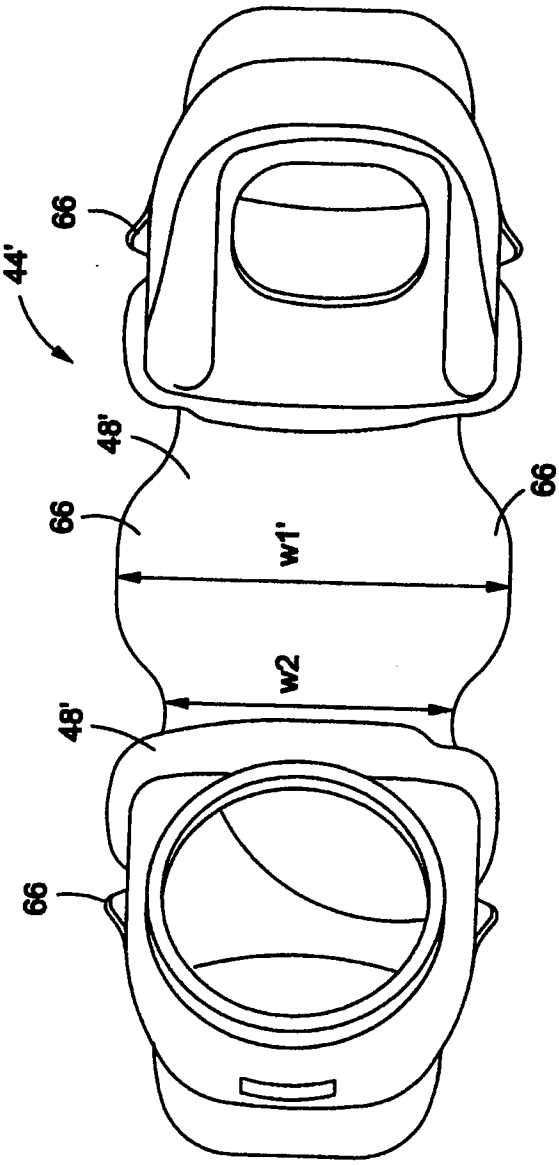
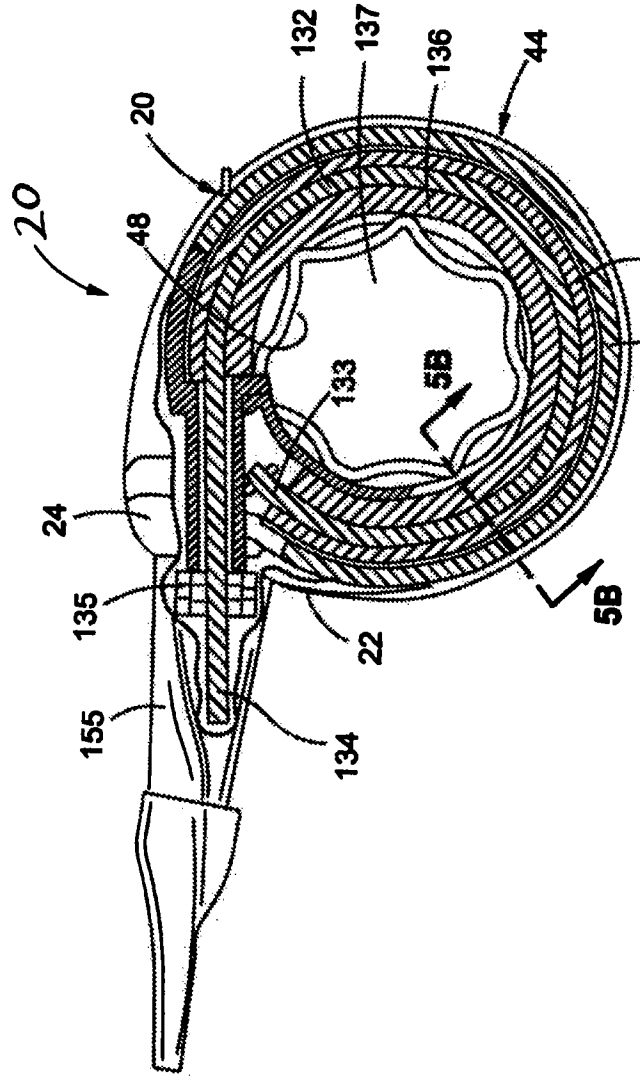


FIG. 4B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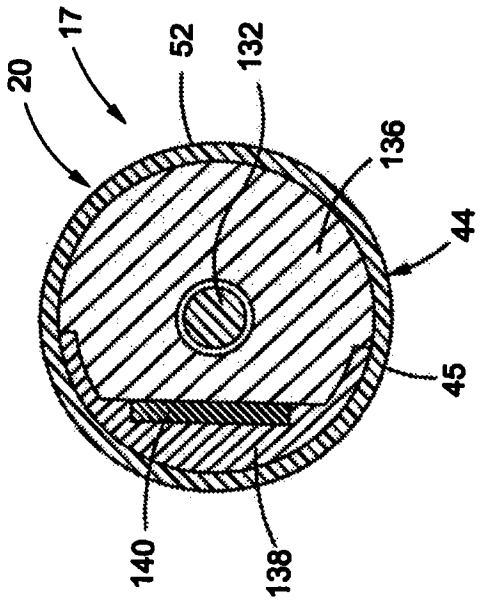
48
132
137
136
44
140
138
133
5B
24
135
22
155
134
5B

FIG. 5A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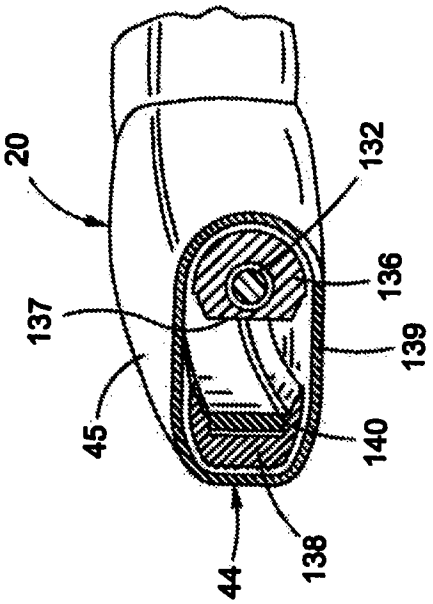
138

FIG. 5B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137
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45
140
44
138

FIG. 5D

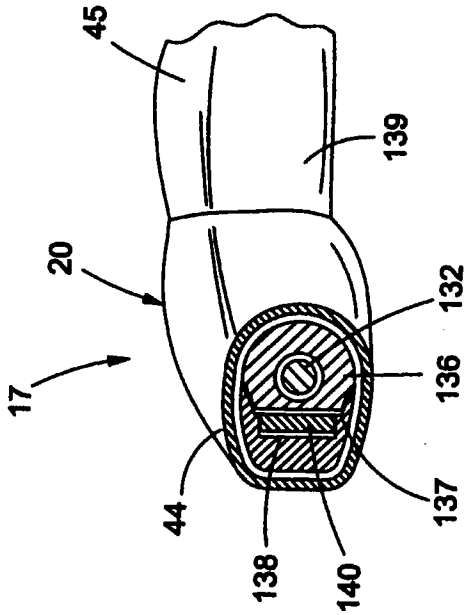

45
139
20
132
17
136
44
137
138
140

FIG. 5C

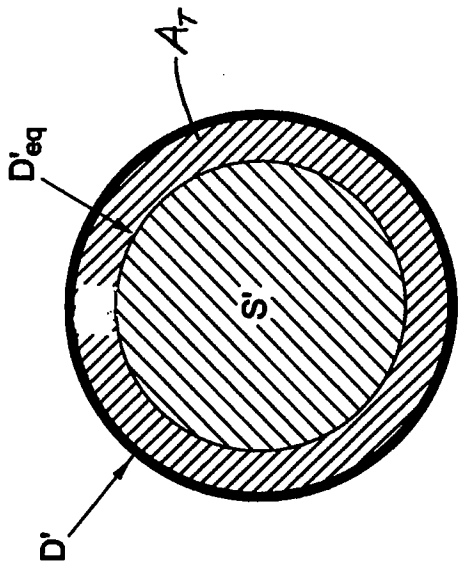


FIG. 5F

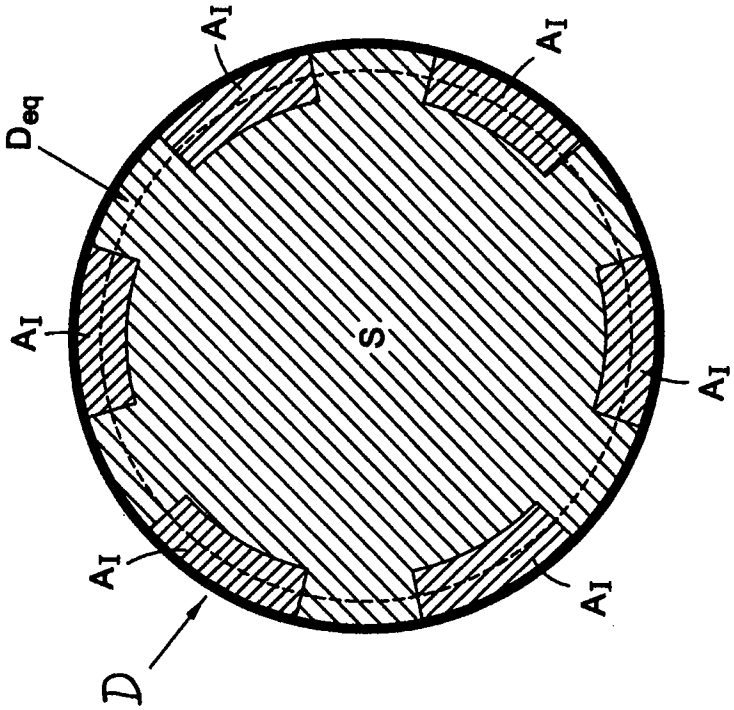


FIG. 5E

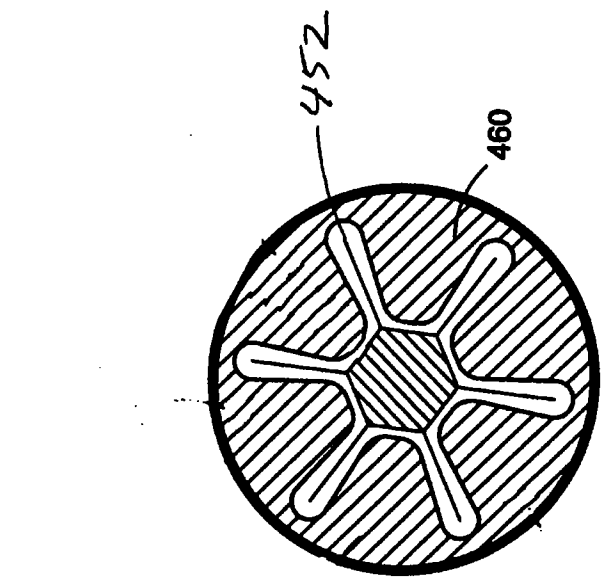


FIG. 5H

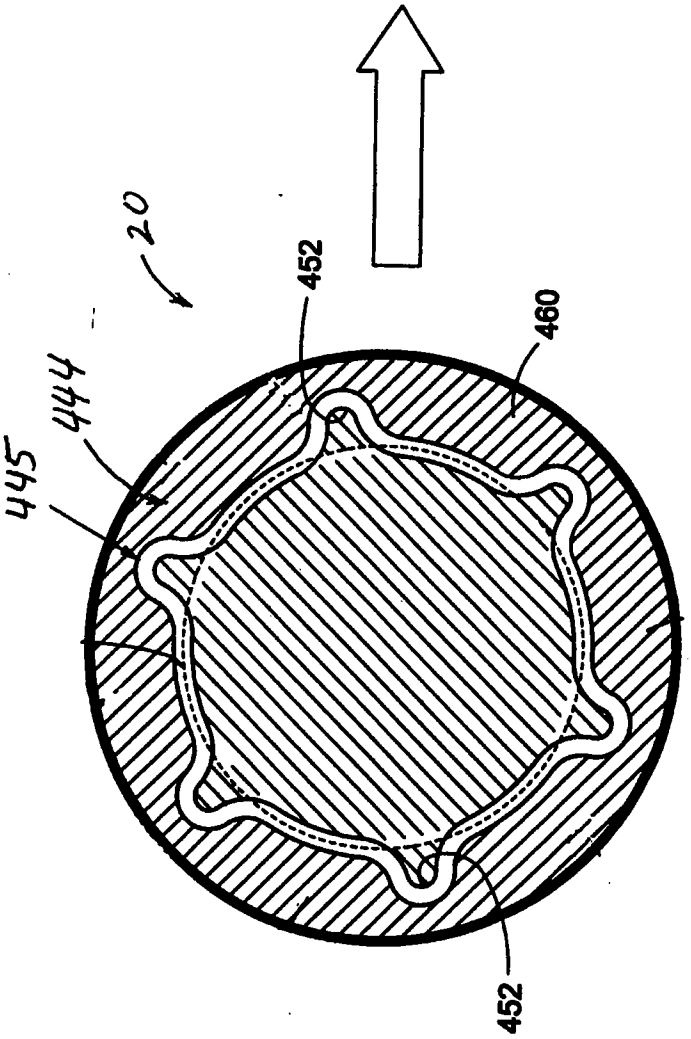


FIG. 5G

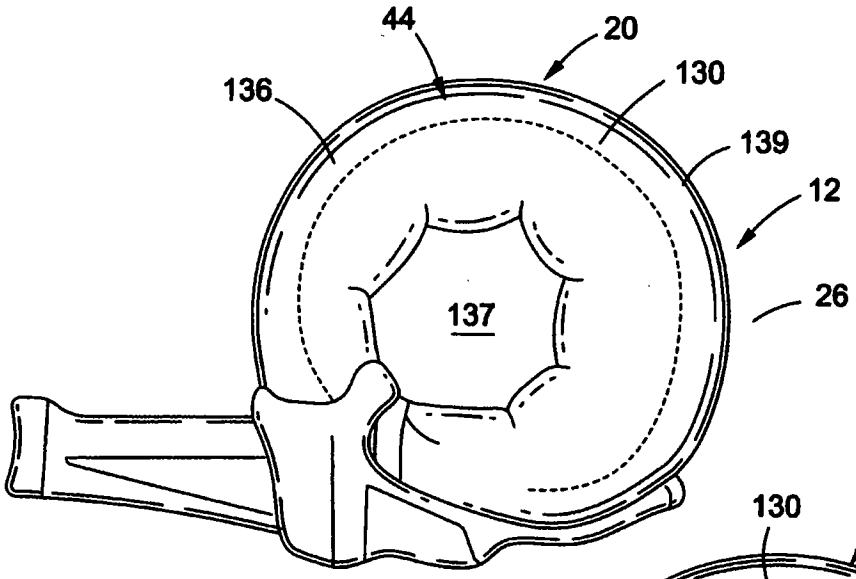


FIG. 6A

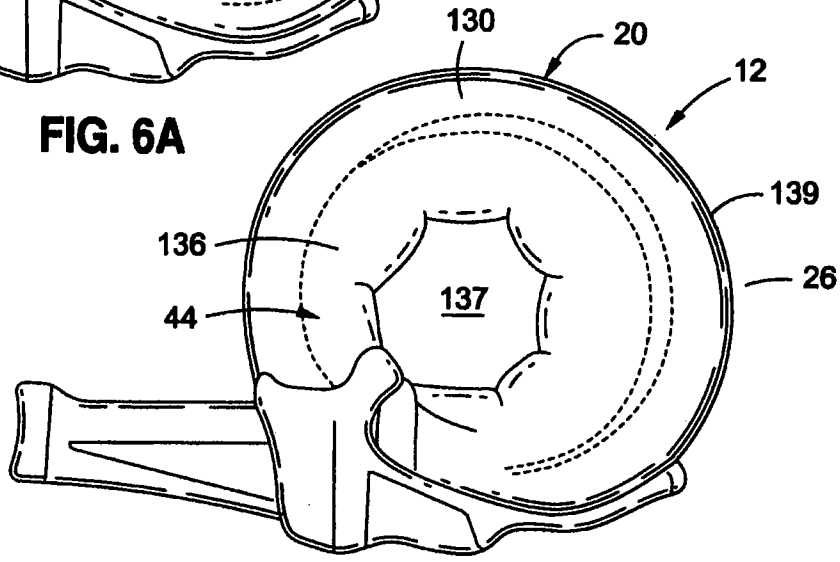


FIG. 6B

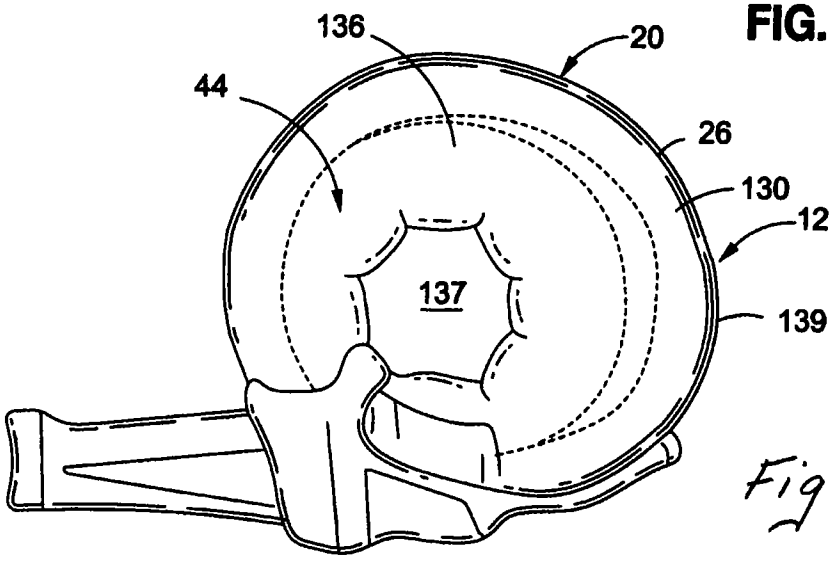


Fig 6C

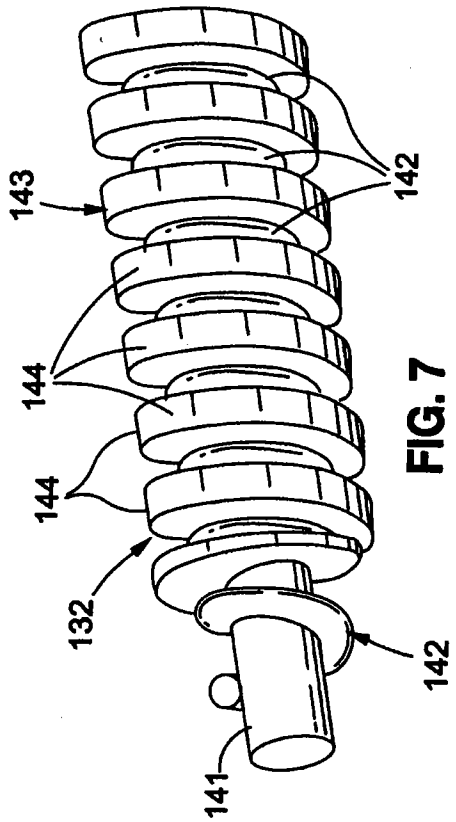


FIG. 7

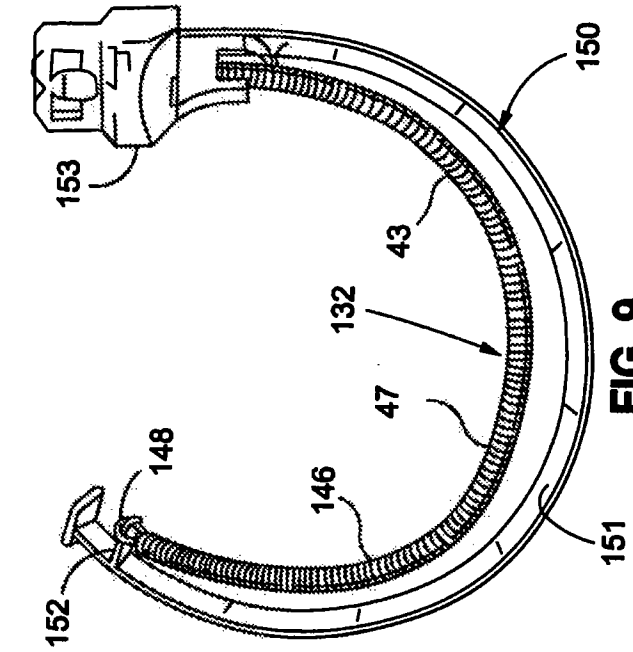


FIG. 9

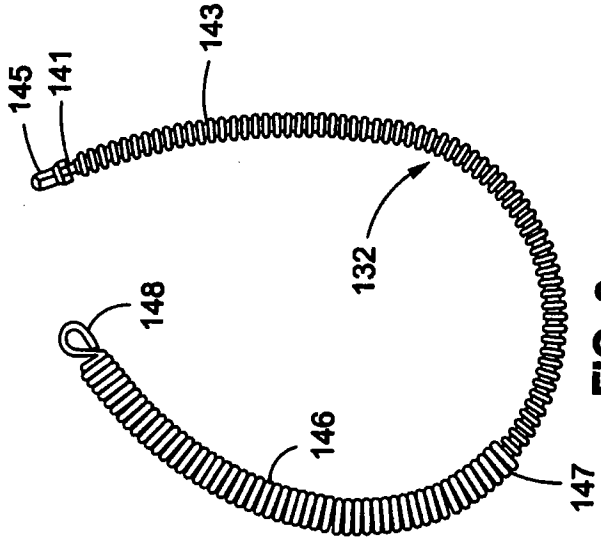


FIG. 8

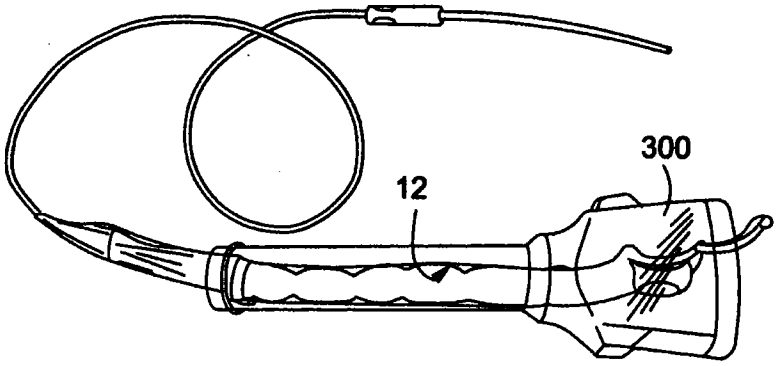


FIG. 10

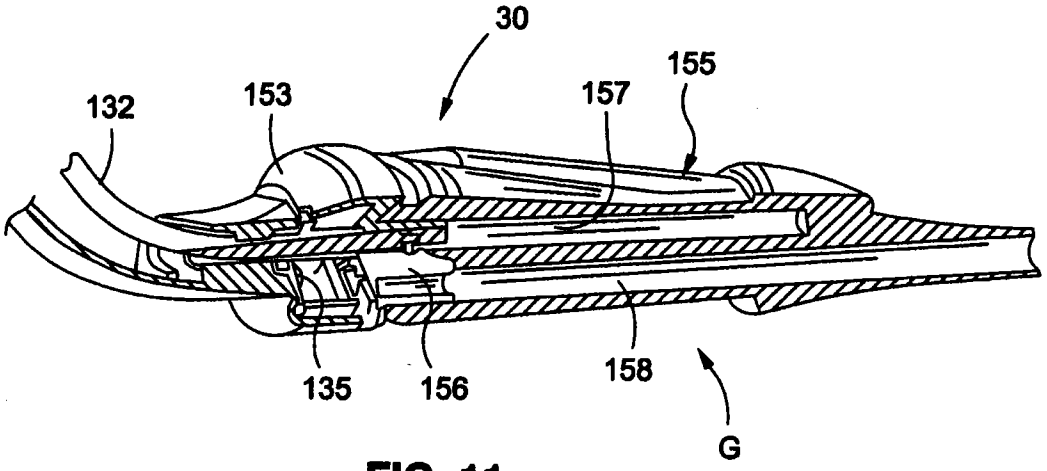


FIG. 11

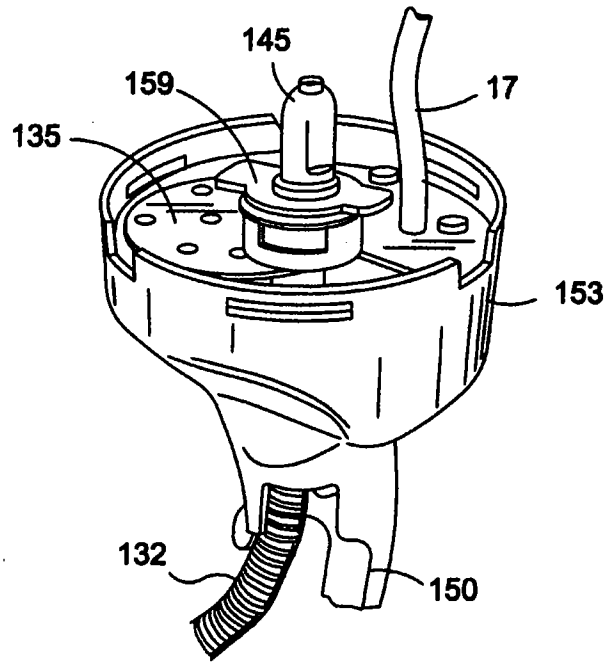


FIG. 12

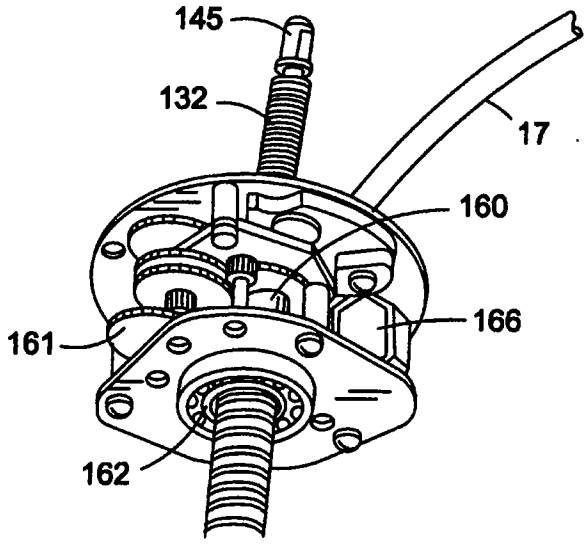


FIG. 13

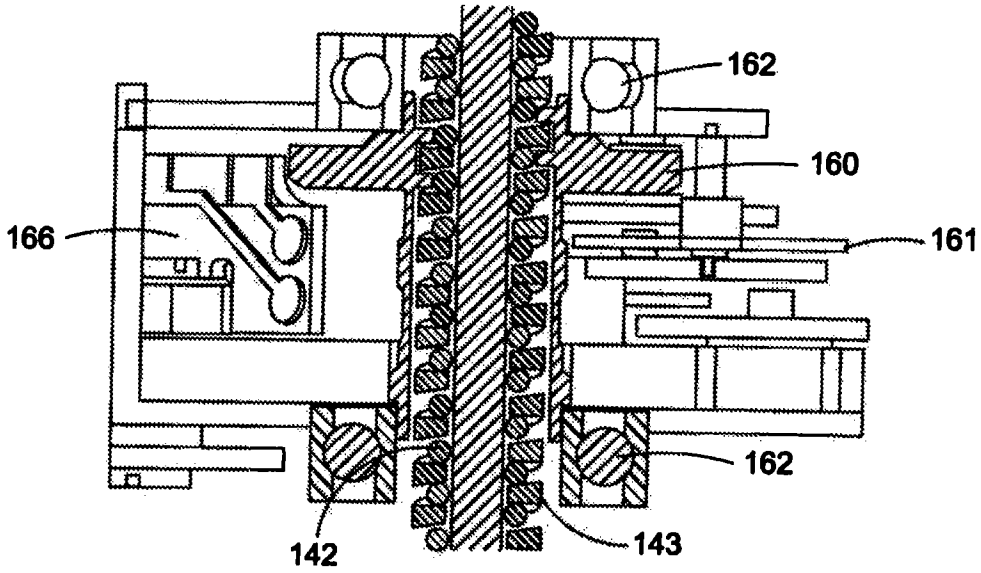


FIG. 14

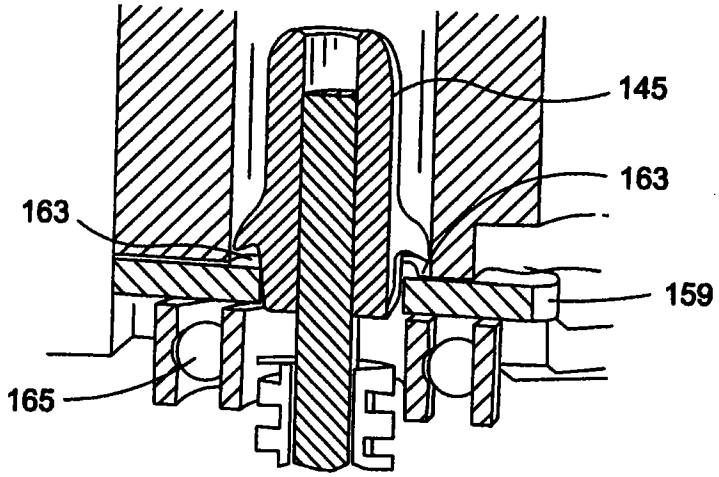


FIG. 15

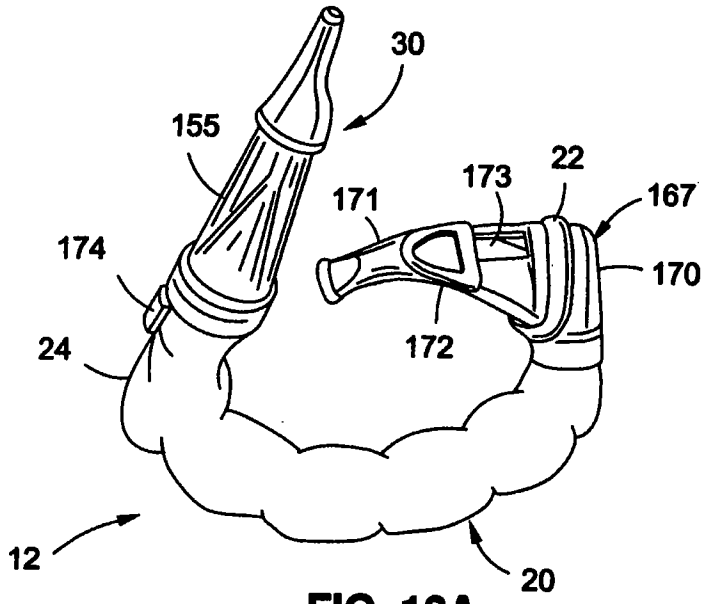


FIG. 16A

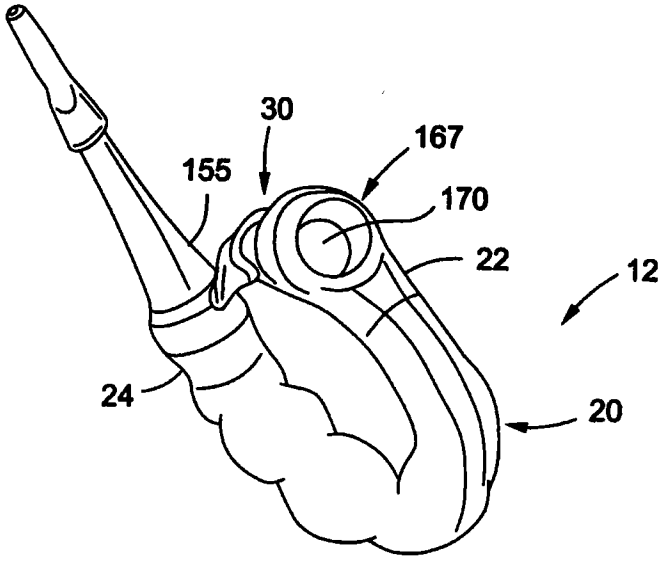


FIG. 16B

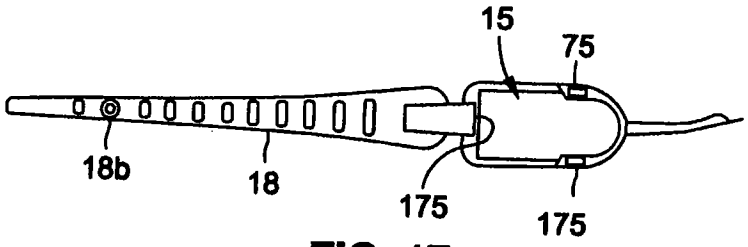


FIG. 17

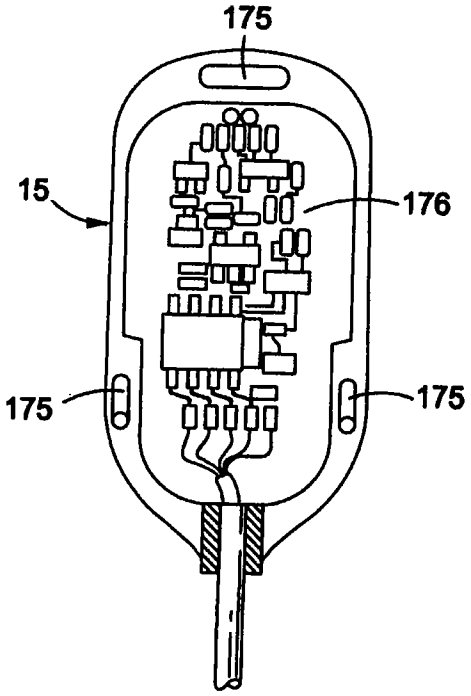


FIG. 18

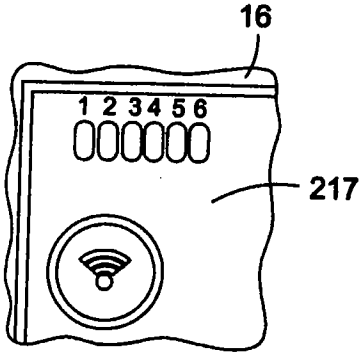


FIG. 20

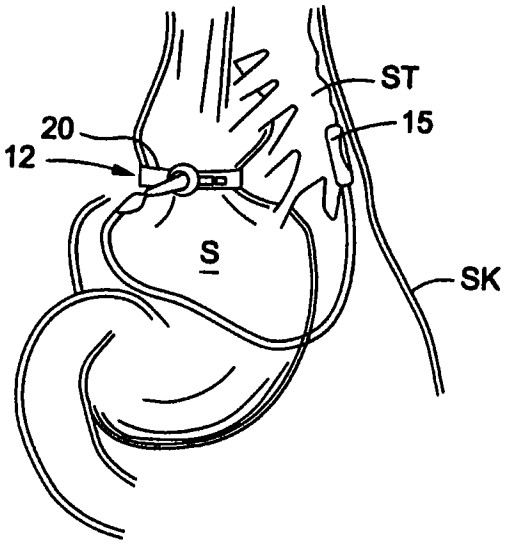


FIG. 21

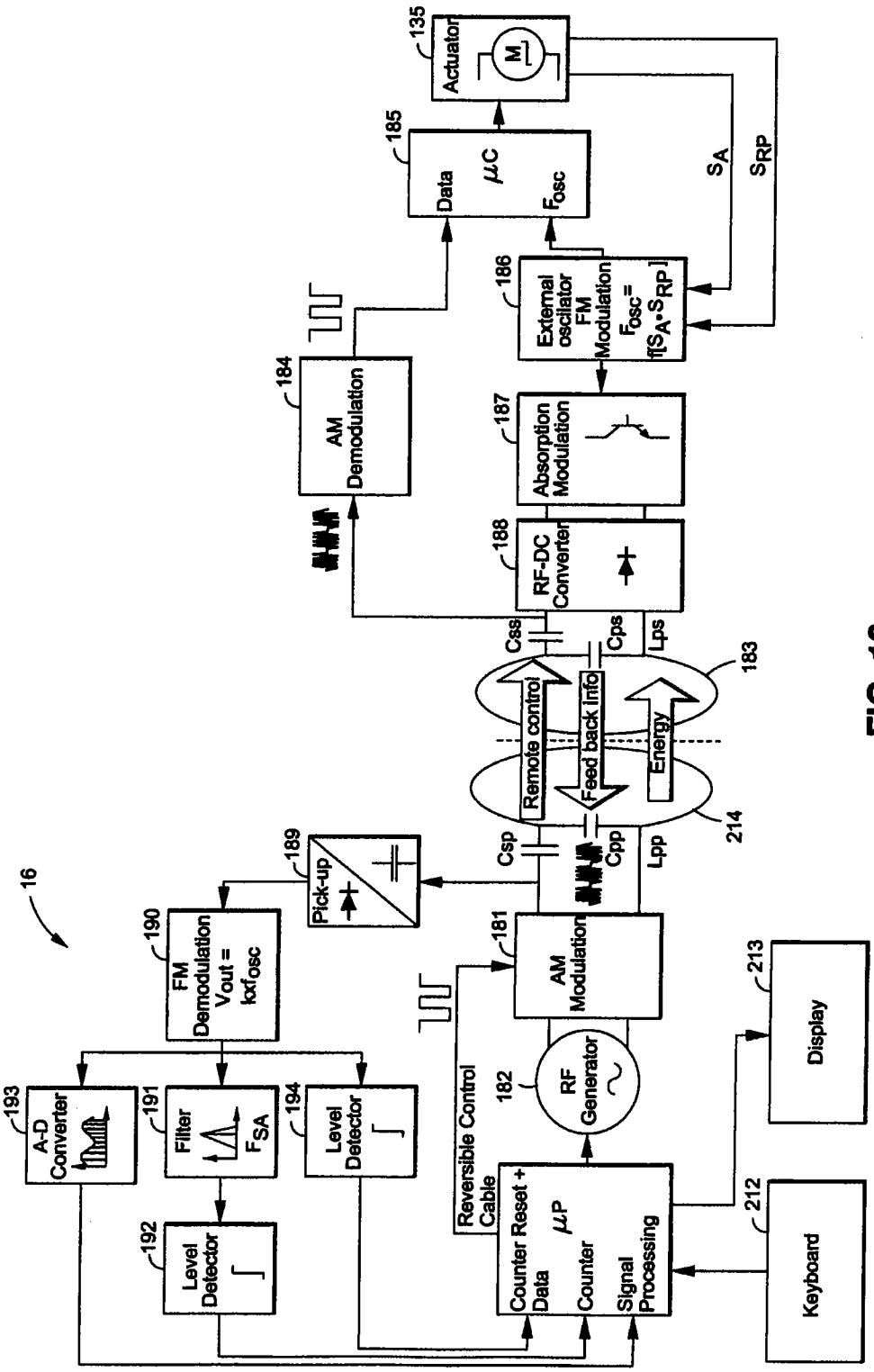

16
135
Actuator
M
185
Data
μC
Fosc
SA
SRP
186
External oscillator FM Modulation
Fosc= f[SA•SRP]
184
AM Demodulation
187
Absorption Modulation
188
RF-DC Converter
Css
Cps
Lps
183
Remote control
Feed back info
Energy
214
189
Pick-up
Csp
Cpp
Lpp
190
FM Demodulation Vout = kxfosc
181
AM Modulation
213
Display
193
A-D Converter
191
Filter
FSA
194
Level Detector
182
RF Generator
Reversible Control Cable
192
Level Detector
Counter Reset + Data
μP
Counter
Signal Processing
212
Keyboard

FIG. 19

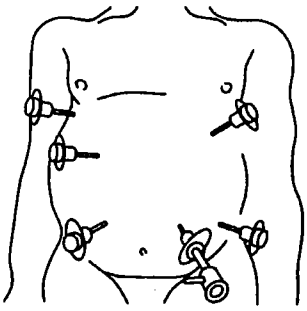


FIG. 22A

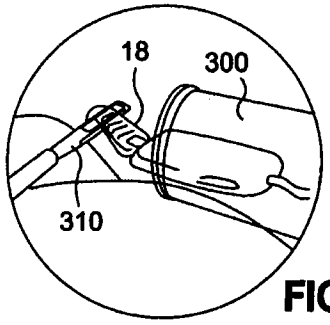


FIG. 22B

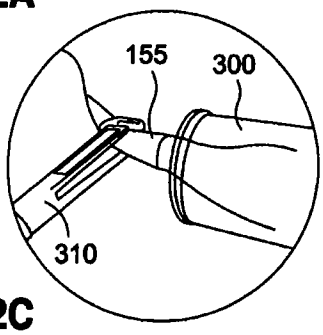


FIG. 22C

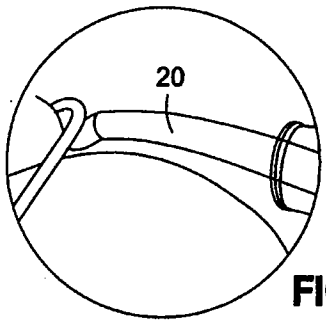


FIG. 22D

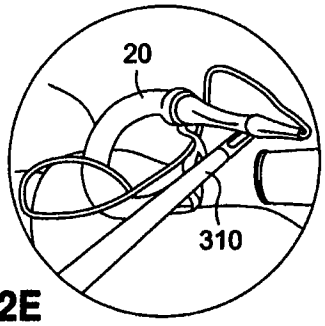


FIG. 22E

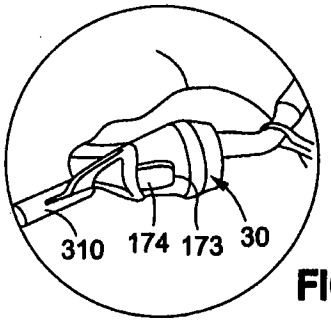


FIG. 22F

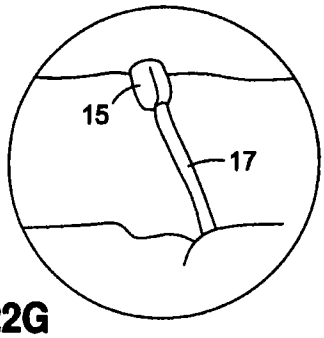


FIG. 22G

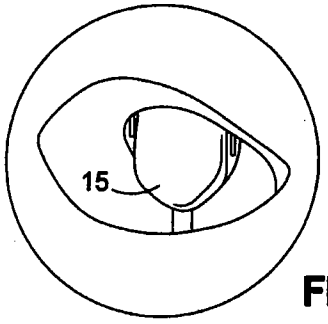


FIG. 22H

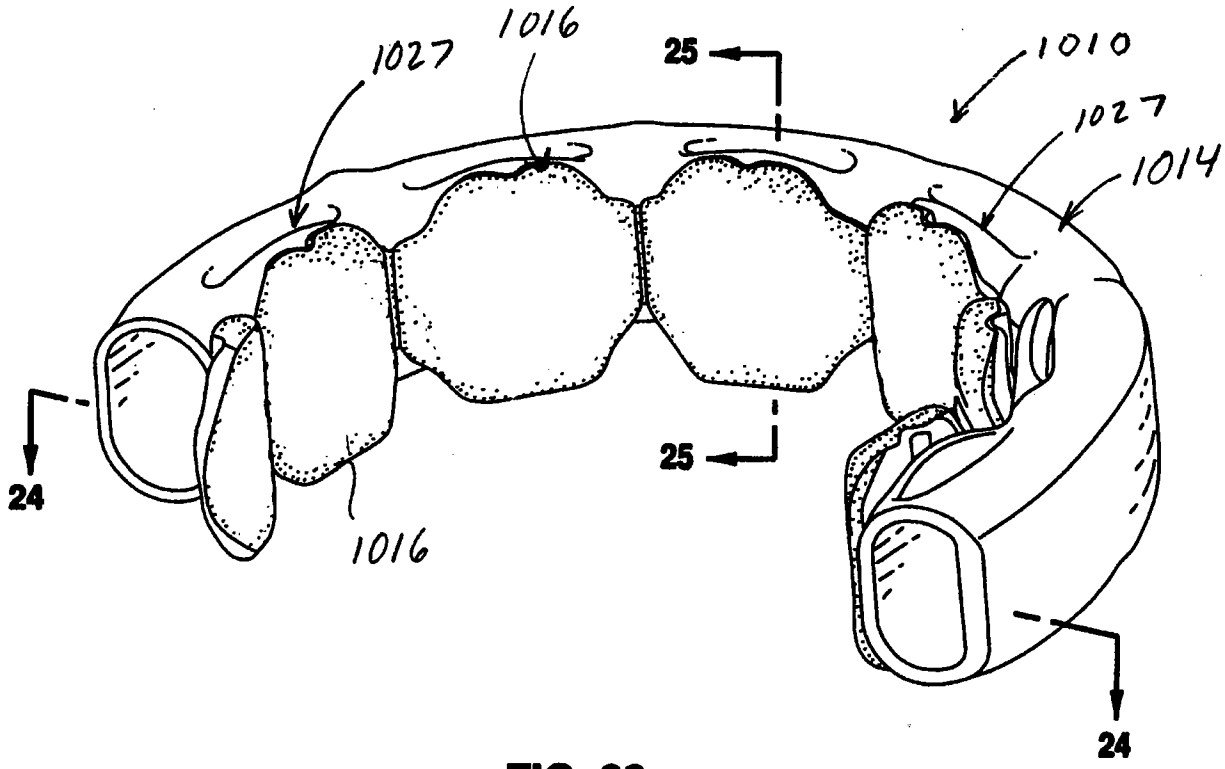
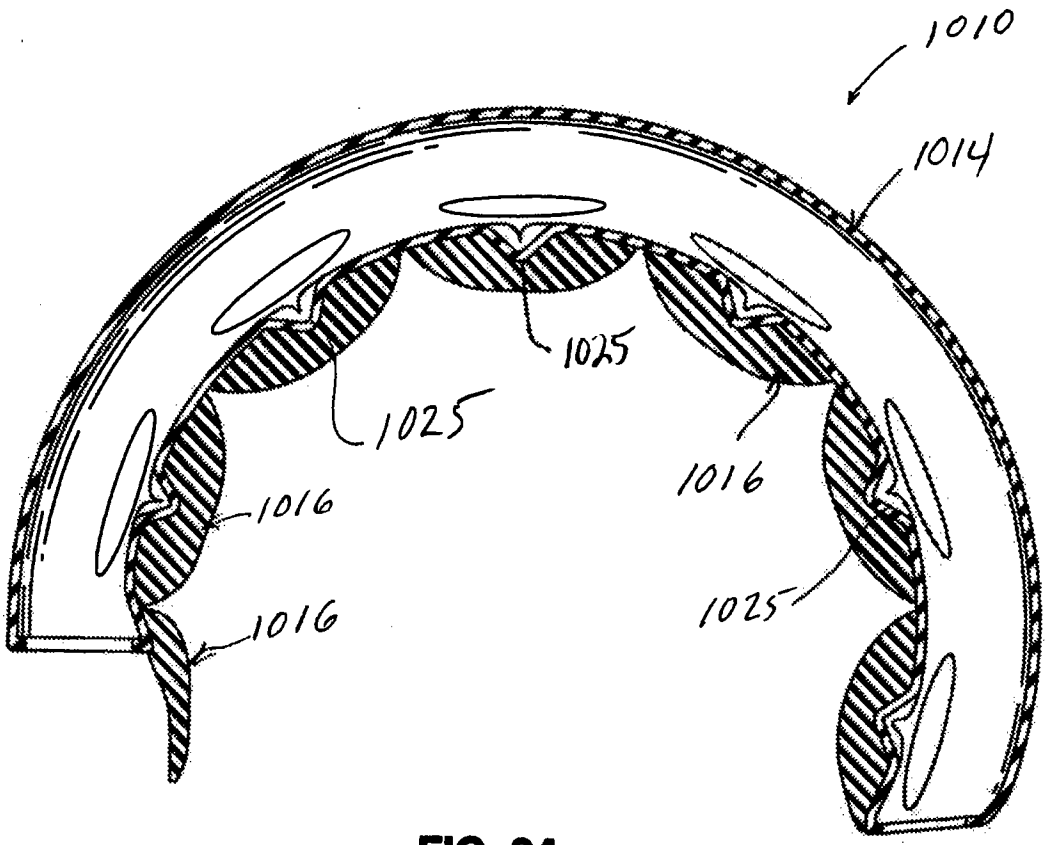


FIG. 23


1010
1014
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1025
1016
1016
1016
1025

FIG. 24

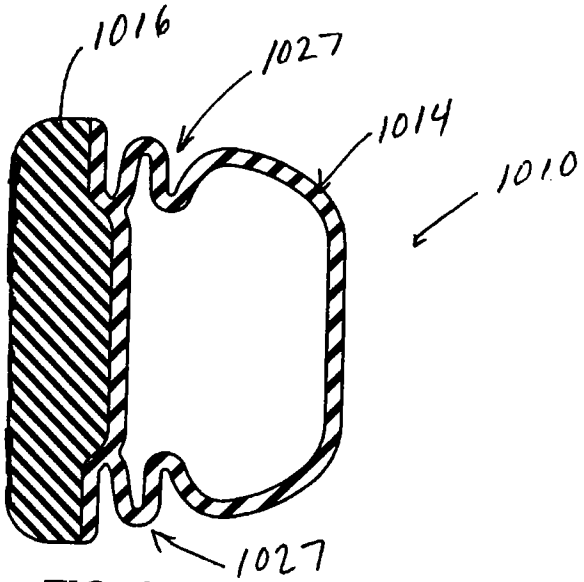
1016
1027
1014
1010
1027

FIG. 25

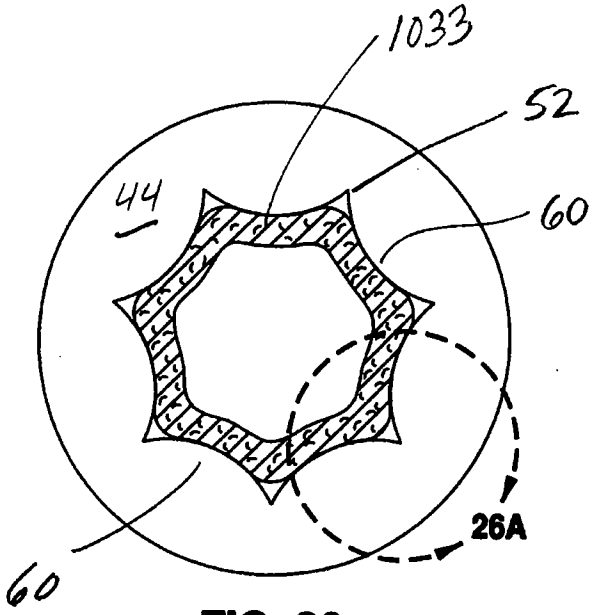

FIG. 26

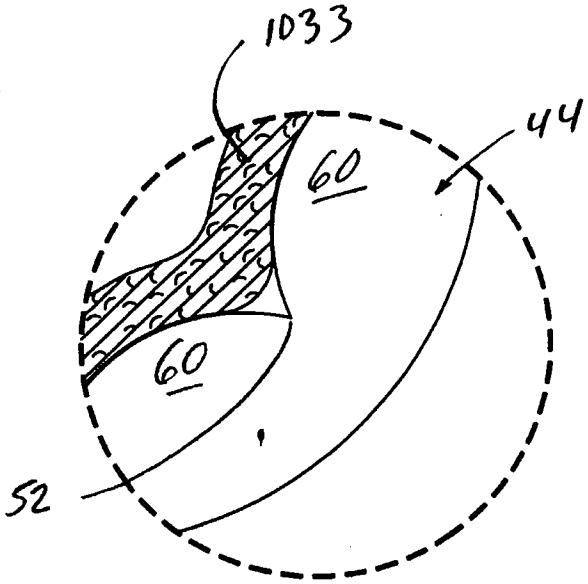

FIG. 26A

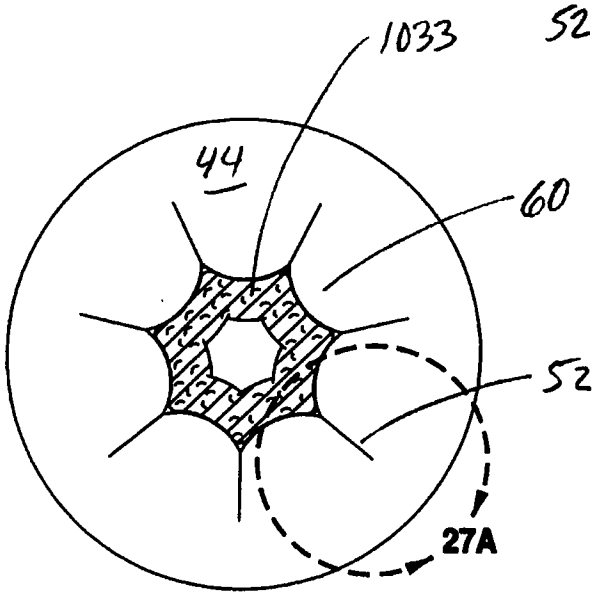

FIG. 27

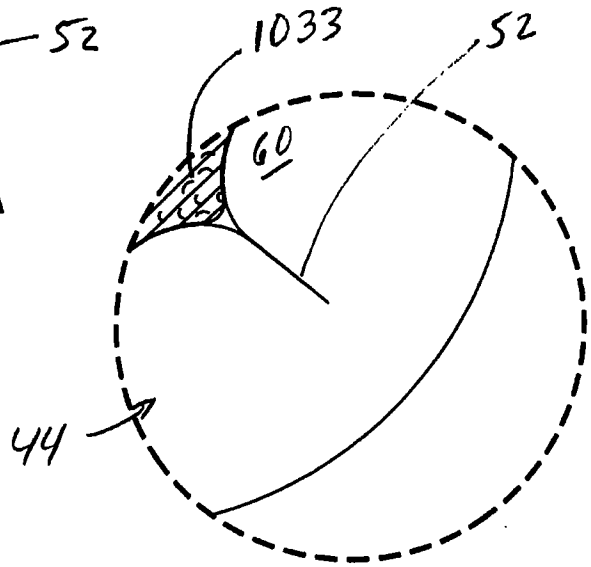

FIG. 27A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/059666

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/09047 A (FORSELL PETER [CH]) 24 February 2000 (2000-02-24) page 23, line 24 - line 29; figures 11-14,28	1-12, 14-21
X	US 6 102 922 A (JAKOBSSON ARNE [FR] ET AL) 15 August 2000 (2000-08-15) column 6, line 15 - column 8, line 54; figures 1-7	1-12, 14-21
P,X	FR 2 921 822 A (BRANCHE DOMINIQUE [FR]) 10 April 2009 (2009-04-10) page 7, line 10 - page 8, line 4; claims 8-12; figures 1,10 page 10, line 11 - line 17	1-12, 14-21
A	WO 2004/019671 A (INAMED MEDICAL PRODUCTS CORP [US]; BIRK JANEL [US]) 11 March 2004 (2004-03-11)	

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 January 2010	02/02/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Sánchez y Sánchez, J

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/059666

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17

A system for regulating an organ or duct, comprising:
-a band having a first end and a second end;
-at least one cushion segment coupled to the membrane and disposed on the proximal region of the band; and
-a mechanism for enabling adjustment of an inner circumference of the loop configuration.

---

2. claims: 18-21

A system for regulating an organ or duct, comprising:
-a band having a first end and a second end;
-a contact region disposed between the first end and the second end of the band;
-the inner circumference of the loop configuration having a generally star-shape defined by the contact region; and
-a mechanism for enabling adjustment of the inner circumference of the loop configuration.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/059666

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 0009047	A	24-02-2000	AT	383834 T	15-02-2008
			AT	294553 T	15-05-2005
			AU	746408 B2	02-05-2002
			AU	5663999 A	06-03-2000
			BR	9912791 A	02-05-2001
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			DE	69938014 T2	08-01-2009
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			ES	2298923 T3	16-05-2008
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FR 2921822	A	10-04-2009	NONE		
WO 2004019671	A	11-03-2004	AU	2003262871 A1	19-03-2004
			BR	0306183 A	19-10-2004
			EP	1553878 A2	20-07-2005
			MX	PA05002361 A	30-09-2005
			US	2005192531 A1	01-09-2005

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 April 2010 (15.04.2010)

PCT

(10) International Publication Number
WO 2010/042493 A1

(51) International Patent Classification:
A61F 5/00 (2006.01)

(21) International Application Number:
PCT/US2009/059666

(22) International Filing Date:
6 October 2009 (06.10.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/103,153 6 October 2008 (06.10.2008) US

(71) Applicant *(for all designated States except US)*: **ALLERGAN, INC.** [US/US]; 2525 Dupont Drive, T2-7h, Irvine, California 92612 (US).

(72) Inventors; and
(71) Applicants : **BERTOLOTE, Tiago** [CH/CH]; 26, rue Tronchin, CH-1202 Geneva (CH). **FRIDEZ, Pierre** [CH/CH]; Champs Jaccoud 11, CH-1055 Froideville (CH).

(74) Agents: **FOX, Linda A.** et al.; Allergan, Inc., 2525 Dupont Drive, Irvine, California 92612 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: MECHANICAL GASTRIC BAND WITH CUSHIONS

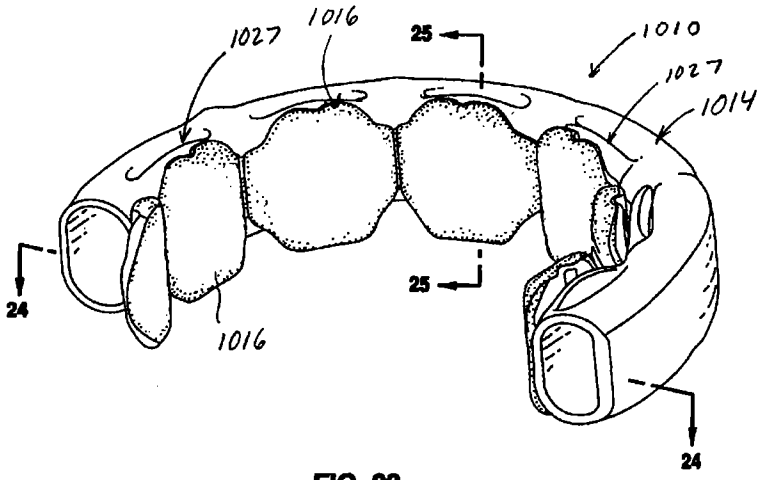


FIG. 23

(57) Abstract: A system for regulating the functioning of an organ or duct generally includes an implantable band structured to at least partially circumscribe an organ or duct and an actuating mechanism operable to effect constriction of the band. The system further includes a plurality of incompressible cushion segments defining a substantially star-shaped inner circumference of the band, the star-shape effective to prevent pinching and necrosis of tissue during adjustment.

WO 2010/042493 A1

MECHANICAL GASTRIC BAND WITH CUSHIONS

By Inventors Tiago Bertolote and Pierre Fridez

RELATED APPLICATION

This application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/103,153, filed on October 6, 2008, the entire disclosure of which is incorporated herein by this reference.

BACKGROUND

This invention relates to surgical devices for regulating or controlling an organ or a duct, for example, a gastric banding system.

Obesity is well recognized as a serious health problem, and is associated with numerous health complications, ranging from non-fatal conditions to life threatening chronic diseases. According to the World Health Organization, debilitating health problems associated with obesity include respiratory difficulties, chronic musculoskeletal problems, skin problems and infertility. Life-threatening problems fall into four main areas: cardiovascular disease problems; conditions associated with insulin resistance such as type 2 diabetes; certain types of cancers, especially the hormonally related and large bowel cancers; and gallbladder disease. Beyond these physiological problems, obesity has also psychological consequences, ranging from lowered self-esteem to clinical depression.

Surgical intervention is sometimes indicated for people suffering from the effects of obesity. Such intervention not only mitigates the myriad health problems arising from being overweight, but may reduce the risk of early death of the patient. Left untreated, morbid obesity may reduce a

patient's life expectancy by ten to fifteen years.

SUMMARY OF THE INVENTION

A system for regulating an organ or duct, for example, the functioning of an organ or duct, is provided. The system generally comprises an implantable band having a first end and a second end, a distal region and a proximal region, and a connector configured to couple the first end with the second end such that the band is formable into a loop configuration. The band is structured to circumscribe, or at least partially circumscribe, an organ or duct, for example, a stomach. The system further comprises a mechanism for enabling adjustment of an inner circumference of the loop configuration to effect constriction of the organ or duct.

For the sake of simplicity, and in no way intended to limit the scope of the invention, the "organ or duct" will hereinafter typically be referred to as a "stomach" and the system will be described as a gastric band system. The band is structured to circumscribe an upper portion of a stomach to form a stoma that controls the intake of food to the stomach. It is to be appreciated that although the invention is hereinafter typically described as pertaining to a gastric band system for application to a stomach, for example, for obesity treatment, the system, with appropriate modification thereto, can be used for regulating or controlling any organ or duct that would benefit from application of the present system thereto.

Once the band is implanted about the stomach, the size of an inner diameter of the band can be adjusted to provide the desired degree of restriction. Techniques for determining appropriate adjustment of gastric bands, timing

and amount of adjustments, are known in the art and therefore will not be described in great detail herein.

Advantageously, in a broad aspect of the invention, the system may be structured to substantially prevent or at least reduce the occurrence of pinching of the body tissues, for example, the tissues of the stomach, during constriction or tightening of the band.

For example, in a specific embodiment, the system further comprises a contact region located between the first end and the second end of the band which is structured and functions to progressively move tissue, for example stomach tissue, during tightening of the band, without entrapping the tissue.

The contact region may comprise plurality of first segments and a plurality of second segments arranged in a generally alternating manner along the proximal (e.g. stomach-facing) region of the band. The first segments may comprise relatively wide, substantially incompressible cushion segments, and the second segments may comprise relatively thin, elastic tension segments. During constriction of the band, adjacent incompressible cushion segments form a progressively narrowing angle, for example, a substantially V-shaped surface. A tension segment is located between the adjacent cushion segments and forms the vertex of the angle or V.

In some embodiments, the cushion segments and tension segments form an inner circumference of the loop configuration having a generally star-shape, defined by the contact region. Deformation of the star-shape during adjustment substantially or entirely prevents pinching of

tissues, as the cushion segments roll forward one another without gaps there-between thus pushing the tissue inwardly.

More specifically, in some embodiments, the contact region defines alternating convex stomach-facing surfaces and concave stomach-facing surfaces. The convex organ facing surfaces may be defined by the cushion segments and the convex organ facing surfaces are defined by the tension segments located between adjacent cushion segments. During constriction of the band, the convex organ-facing surfaces may maintain their shape while folding at the tension segments inwardly toward one another. This mechanism and structure causes the tissues of the stomach to be pushed outwardly from the band constriction without the tissues becoming entrapped and/or pinched by the contact region.

In addition, the structure of the contact region, including cushion segments and tension segments, may be advantageously structured to maintain mechanical stability of the band. For example, the tension segments provide a means for maintaining positioning of the cushion segments and by substantially preventing the contact region of the band from creasing, folding or rolling out of position while the band is implanted in the body around the duct or organ, for example, the stomach.

In some embodiments, the contact region comprises a membrane, for example, a somewhat tubular-shaped elastic membrane encompassing, secured to or defining the cushion segments. In one embodiment, portions of the membrane may form the tension segments between adjacent cushion segments.

In one embodiment, the cushion segments are formed of individual incompressible molded elements in contact with or spaced apart from one another, and affixed to the membrane.

The cushion segments may be spaced apart by portions of the elastic membrane which are stretched under tension.

The cushion segments may be located on an internal surface of the membrane or alternatively may be located on an external surface of the membrane. In one embodiment, the cushion segments are located on an external surface of the membrane and are overmolded to the membrane.

In another feature of the invention, membrane may include structure, for example, corrugations or indentations, for facilitating expansion of the membrane during adjustment of the loop. For example, such corrugations can be located and structured to minimize the force required to elongate or stretch the membrane in the radial direction during tightening of the band. The corrugated surfaces of the membrane reduce membrane deformation energy by allowing the membrane to unfold rather than stretch during adjustment.

The mechanism for enabling adjustment may comprise an electronic interface, for example, an implantable electronic interface, connected to the band, and a control, for example an external control unit, capable of communicating with the interface to regulate the constriction of the band about said organ or duct.

These and other features of the present invention may be more clearly understood and appreciated upon consideration of the following Detailed Description and the accompanying Drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a schematic representation of one embodiment of the present invention, the system including a band including a contact region, an interface including an antenna/controller pod, and an external control.

Fig. 2 shows a perspective, cutaway view of the contact region shown in Fig. 1.

Fig. 3 shows a perspective view of the contact region shown in Fig. 1.

Fig. 3A shows a cross-sectional view of the contact region taken along lines 3A-3A of Fig. 3.

Fig. 4A shows an elevation view of the contact region shown in Fig. 1.

Fig. 4B shows an elevation view of an alternative contact region in accordance with another embodiment of the invention.

Fig. 4C shows a perspective view of the alternative contact region shown in Fig. 4B.

Fig. 5A shows a cross-sectional view of the band shown in Fig. 1.

Fig. 5B shows a cross-sectional view of the band taken along lines 5B-5B of Fig. 5A.

Fig. 5C shows a perspective, cutaway view of the band in a fully open position.

Fig. 5D shows a perspective, cutaway view of the band in a constricted position.

Figs. 5E and 5F are schematic representations of an amplified adjustment feature of an embodiment of the present invention.

Fig. 5G and 5H are simplified schematic representations of another embodiment of the invention.

Figs. 6A through 6C show plan views of the band at different levels of constriction.

FIG. 7 is a partial perspective view of a screw thread portion of a tension element useful in the band of the system of the invention.

FIG. 8 is a perspective view of an entire tension element shown in Fig. 7.

FIG. 9 is a perspective view of the tension element of FIG. 8 coupled to a rigid distal peripheral portion in the band of the system of the invention.

FIG. 10 is a perspective view of the band of the system in a straightened configuration and located within a trocar to facilitate implantation.

FIG. 11 is a cross-sectional view of an actuator housing on an end of the band.

FIG. 12 is a perspective view of an actuator in the housing shown in Fig. 11.

FIG. 13 is a perspective of the tension element engaged with the actuator shown in Fig. 12.

FIG. 14 is a cross-sectional view depicting the construction of the actuator shown in Fig. 12.

FIG. 15 is a cross-sectional view depicting the construction of a reference position switch useful in the system of the invention.

FIGS. 16A and 16B are perspective views illustrating a clip used to close the band of the system of the invention.

FIG. 17 is a perspective view of the antennae/controller pod of the system shown in Fig. 1.

FIG. 18 is a cut-away view of the interior of the implantable antenna/controller pod.

FIG. 19 is a schematic view of telemetric power and control circuitry useful in systems of the invention.

FIG. 20 is a view of a signal strength indicator portion of the control shown in Fig. 1.

FIG. 21 is a schematic diagram illustrating placement of the implantable portions of the system of the invention.

Each of FIGS. 22A-22H is a view illustrating steps in a method of laparoscopically implanting the system of the present invention.

Fig. 23 is a perspective view of a contact region including a membrane and overmolded incompressible cushions of a gastric band of the present invention.

Figs. 24 and 25 are cross sectional views of the contact region shown in Fig. 23 taken along line 24-24 and line 25-25, respectively.

DETAILED DESCRIPTION

Turning now to Fig. 1, an embodiment of a system of the present invention is generally shown at 10. In one aspect of the invention, the system 10 is useful for regulating the functioning of an organ or duct (not shown) for example, a stomach. In one embodiment, the system 10 is a gastric banding system useful in the treatment of obesity and/or obesity related diseases.

It is to be understood that although much of the following description is generally directed to gastric banding systems of the invention, the present invention is in no way limited thereto. Other embodiments of the invention may be applied to regulate the functioning of other body organs or ducts, such as in the treatment of gastro-esophageal reflux disease, urinary or fecal incontinence, colostomy, or to regulate blood flow.

In this exemplary embodiment, the system 10 generally comprises an implantable portion 12 including an adjustable band 20, an interface 14 including an antenna/controller pod 15, and a control 16 in communication, for example, telemetric communication, with the pod 15. Pod 15 may be connected to the band 20 by means of antenna cable 17 and may include removable tag 18 for facilitating laparoscopic positioning thereof.

Laparoscopically implanted gastric bands and their use in the treatment of obesity are now well known. Generally,

in accordance with the present invention, the band 20 is structured to be implantable in a patient, for example, laparoscopically implantable, around an upper region of the patient's stomach, thereby forming a stoma that restricts food intake and provides feelings of satiety. The inner diameter of the band 20 is adjustable in vivo in order to enable a physician or patient to achieve most desirable stoma size, and the best clinical results.

The band 20 includes a first end 22 and a second end 24, a distal region 26 and a proximal region 28, and a connector 30 configured to couple the first end 22 with the second end 24 of the band 20 such that the band 20 is formable into a loop configuration, as shown.

When the band 20 is formed into said loop configuration, the proximal region 28 forms an inner circumferential surface which at least partially circumscribes and contacts the organ or duct, for example, the stomach, to be regulated or controlled.

Generally, by loosening or tightening the band 20 about the stomach, regulation and/or functioning of the stomach can be controlled or adjusted. When not connected at first and second ends 22, 24, the band 20 can be temporarily straightened in order to facilitate surgical implantation, for example, via laparoscopic techniques.

The system 10 further comprises a contact region 44 disposed between the first and the second ends 22, 24 of the band 20. Turning now to Figs. 2 and 3, the contact region 44 may comprise, at least in part, an elastic component made of, for example, a molded silicone elastonomer. The elastic component comprises a membrane 45 having a generally tubular form which covers or encases the internal mechanisms of the

band 20, for example, gastric band tightening mechanisms such as those to be described hereinafter. The membrane 45, when at rest, may have an arcuate or C-shaped form.

As shown in Fig. 2, contact region 44 comprises first segments 48 and second segments 52 arranged in a generally alternating manner. The first segments 48 may be defined by generally planar and/or convex stomach-facing surfaces, i.e. proximal surfaces, of the contact region 44. The second segments 52 may be defined by generally concave exterior surfaces generally forming indentations between the first segments 48.

In some embodiments, the first segments 48 comprise cushion segments 60. The cushion segments 60 are spaced apart from one another by the second segments 52. The cushion segments 60 may be made of non-compressible material, for example, a silicone elastomer.

In one aspect of the present invention, a suitable incompressible material making up the cushions is a moldable material that has substantially constant density throughout and maintains its volume when deformed. The volume of incompressible materials cannot be reduced more than a nominal amount (e.g., about 5%) when subjected to static compression, or external pressure. The cushions may be a soft silicone material that is a deformable, resilient solid or a gel.

The cushion segments 60 may be made of a material that has a different durometer, for example, is softer, than the material forming the membrane 45. In a specific embodiment, the cushions comprise a soft, molded silicone elastomer material having hardness of 5 Shore A. The membrane

comprises a soft molded silicone elastomer material having a hardness of 30 Shore A.

In one embodiment, cushions 60 may be structured to provide form, definition, support and/or structural integrity to the first segments 48. The second segments 52 may be portions of the membrane 45 which are stretched under tension. The second segments may be structured to provide stability to the contact region 44 and to maintain positioning, for example, circumferential positioning, of the cushions 60 during use of the system 10.

Turning now specifically to Fig. 3, the first segments 48 may have a first axial width W1, and the second segments have a second axial width W2 which is less than the first axial width W1.

In the shown embodiment of the invention, the contact region 44 includes seven first segments 48 (including 48'), each first segment being generally equally spaced apart by intermediate second segments 52. In other embodiments of the invention, contact region 44 includes at least three first segments, at least four first segments, at least five first segments, or at least six first segments. In other embodiments of the invention, the contact region 44 includes more than seven first segments, for example, up to ten first segments or more.

In another aspect of the invention, membrane 45 may be structured to facilitate expansion in a radial direction during adjustment of the inner circumference of the band 20. For example, turning now to Fig. 3, membrane 45 may include radially expandable surfaces 56. For example, membrane 45 includes one or more corrugations 58.

In the shown embodiment, the corrugations 58 are generally aligned with the cushion segments 60. As shown in Fig. 3A, the corrugations 58 may be defined by convolutions 58a defined in an upper surface and lower surface of the membrane 45. The corrugations 58 may be placed to minimize the force required by the actuating mechanism to elongate the membrane 45 in the radial direction. Rather than requiring excessive stretching of the membrane, the membrane unfolds during adjustment.

In the shown embodiment, certain first segments 48 include corrugations 58 and other first segments (e.g. first segments 48') do not include corrugations. For example, intermediate first segments 48 include corrugations 58 and terminal first segments 48' do not include corrugations.

The presently described and shown corrugated structure of the contact region 44 may function to facilitate controlled expansion and/or contraction of the first segments 48, for example, during adjustment of the inner circumference of the band. In some embodiments of the invention, the corrugated surfaces 56 function, at least in part, to decrease the level of force required to adjust the inner circumference of the loop.

In some embodiments, the contact region 44 includes first cushions 60 and second cushions 60a which are configured somewhat differently than first cushions 60. In the shown embodiment, first cushions 60 are located on intermediate first segments 48 and second cushions 60a are located on terminal first segments 48' (i.e. those first segments located at the extremities of the contact region 44).

More specifically, in the embodiment shown in Fig. 2, each first cushion 60 includes a substantially planar or convex face 61 and at least one or more distal projections 62. For example, each cushion 60 includes three longitudinal, arcuate projections 62 as shown. A cross-sectional view of first cushion 60 having these features is also shown in Fig. 3A.

Fig. 4A shows an elevation view of the contact region 44 (cushions not shown) in order to illustrate width W1 of first segment 48 relative to width W2 of second segment 52 of contact region 44. In an exemplary embodiment of the invention, W1 is about 17 mm and W2 is about 13 mm.

Fig. 4B shows an elevation view of an alternative contact region 44' in accordance with the invention. Contact region 44' is identical to contact region 44 shown in Fig. 4A, with a primary difference being that first segment width W1' of contact region 44' is greater than first segment width W1 of contact region 44. That is, W1' > W1. The additional width of first segment width W1' is provided by upper and lower protuberances 66 on first segments 48'. In an exemplary embodiment, W1' is about 19 mm and W2 is about 13 mm. Fig. 4C shows a perspective view of contact region 44' having first segments 48' with protuberances 66.

Turning now to Figs. 5A-5D, an exemplary inner mechanism of the band 20 which enables adjustment of the inner circumference of the loop configuration will now be described. Band 20 may comprise a flexible tension element 132 having fixed end 133 mounted to first end 22 of band 20 and another end 134 that is coupled to an actuator 135 at second end 24 of adjustable element 20. Tension element 132 is slidingly disposed within a substantially cylindrical

tube of axially compressible material 136. When tension element 132 is pulled through actuator 135, compressible material 136 is compressed and the diameter of loop opening 137 is reduced.

Turning now specifically to Figs. 5B through 5D, compressible material 136 may be surrounded on a distal face 137 thereof with a flexible, relatively sturdy elastomeric material, such as silicone element 138. Both compressible material 136 and silicone element 138 are enclosed within the membrane 45 of contact region 44.

In one aspect of the invention, the band 12 may be structured to provide an amplified adjustment feature. This concept is illustrated in Figs. 5E and 5F, and in Figs. 26 thru 27A.

The incompressible cushion segments 60 provide enhanced and more efficient control of adjustment of the inner diameter of the band 20. Figs. 5E and 5F are schematic representations of the cross-section of the band in the open configuration and constricted configuration, respectively. Outer diameter D represents the outer diameter of axially adjustable portion of the band 20. Areas of individual cushion regions 60 are represented by areas A_I in Fig. 5E (open configuration). The total area occupied by the individual cushion regions is represented as annular area A_T in Fig. 5F (constricted configuration). Surface S represents the available lumen around the stomach (or other organ or duct being controlled or regulated) and diameter Deq represents an equivalent diameter, that is, the diameter of a circle having the same surface area as S.

When the loop is constricted from the fully open state, diameter D (Fig. 5E) becomes D' (Fig. 5F), the surface S

becomes S' and the equivalent diameter Deq becomes D'eq. Because the cushions occupying A_I are incompressible, the total surface area A_T occupied by the cushions does not change. The equivalent diameter Deq decreases more rapidly than the diameter D.

For example, D=29mm in a fully open position and a total surface of the incompressible cushions A_T equal to about 120 square mm: S=540.52 sq mm and Deq=26.2mm. When in fully closed position, D'=19mm: S'=163.53 sq mm, and D'eq=14.4. Thus D-D'=10mm, and Deq-D'eq=11.8mm, which provides an "amplification factor" of about 1.18. Thus, by changing the values of D, D' and A_T, the amplification factor can be controlled.

The substantially incompressible cushion segments allow a relative restriction of the lumen during adjustment greater than without substantially incompressible cushion segments. That greater relative restriction arises from the fact that the cross-section of the substantially incompressible cushion segments remains constant during adjustment, whereas the area of the lumen decreases during closure, so that the ratio (cushion cross-section)/(lumen) increases. Accordingly, the substantially incompressible cushion segment effect on lumen restriction increases during closure.

Figs. 5G and 5H show a simplified schematic representation an embodiment of the invention in which contact region 444 comprises an elastic membrane 445 and a single continuous, incompressible cushion segment 460 instead of the individual, separate cushion segments 60 shown in Fig. 2. Other than cushion segment 460 being a single substantially continuous cushion segment rather than a plurality of individual separate cushion segments 60, the

band 420 may be identical to band 20. The continuous cushion segment 460 is configured or shaped to accommodate tension segments 452 of the membrane 445. For example, the continuous cushion segment 460 has a variable thickness, with the thickest regions functioning similarly to incompressible cushion regions 60 described elsewhere herein. Fig. 5H shows bending of tension regions 452 and deformation of incompressible cushions 60 during the constriction of the loop.

Turning back to Fig. 5A, band 20 may further comprise member 140 of a relatively rigid material. By its structural rigidity, member 140 imposes a generally circular arc shape for the entirety of band 20. In some embodiments of the invention, rigidity of band 140 functions to prevent the exterior diameter of band 12 from changing during adjustment of the internal diameter of the loop.

Generally, an increase or reduction of the length of tension element 132 results in reversible radial displacement at the internal periphery of the band 20. This in turn translates into a variation of internal diameter of the loop from a fully open diameter to a fully closed diameter.

In various embodiments of the invention, the diameter of the opening 137 formed by the band 20 may be between about 25 mm or about 35 mm in a fully dilated position (e.g. see Fig. 5C). The diameter of the opening 137 may be between about 15 mm and about 20 mm when the band 20 is in a fully constricted position (e.g. see Fig. 5D).

Figs. 6A, 6B and 6C show the band 12 at progressively increased levels of constriction, with Fig. 6A showing the opening 137 being larger than in Fig. 6B, which shows the

opening 137 larger than in Fig. 6C. In the shown embodiment of the invention, while diameter of opening 137 is adjustable, the diameter an outer circumferential surface 139 of the band 12 remains relatively fixed during adjustments of the opening 137. Membrane 45 of contact region 44 stretches or unfolds as described elsewhere herein, as axially compressible material 136 moves apart from distal element 130 and band (not visible in Figs 6A-6C) and opening 137 constricts. (See also Fig. 5D).

Referring now to FIG. 7, tension element 132 is described. In some embodiments, tension element 132 has sufficient flexibility to permit it to be formed into a substantially circular shape, while also being able to transmit the force necessary to adjust the inner diameter of the loop. Tension element 132 may comprise flexible core 141, for example, comprising a metal alloy wire of circular cross section, on which is fixed, and wound coaxially, at least one un-joined coil spring which defines a screw thread pitch.

Tension element 32 may comprise two un-joined coil springs that form a screw thread: first spring 142, wound helicoidally along the flexible core 141, and second spring 143 of greater exterior diameter. Second spring 143 preferably comprises coils 144 of rectangular transverse section, so as to delineate a flat external generatrix. First spring 142 is interposed between coils 144 of the second spring 143 to define and maintain a substantially constant square screw thread pitch, even when the tension element is subjected to bending.

Second spring 143 may be made by laser cutting a cylindrical hollow tube, e.g., made from stainless steel, or alternatively, by winding a wire with a rectangular,

trapezoidal or other cross-section. When helically intertwined with first spring 142, coils 144 of second spring 143 are activated with an intrinsic elastic compression force from the adjacent coils of first spring 142. First spring 142 is intertwined between the coils of second spring 143. First spring 142 is fixedly joined to flexible core 141 at one end. At the second end, a crimped cap 145 (see FIG. 8) is located a short distance from the ends of springs 142 and 143 to allow for small extensions, for example, to accommodate flexion of tension element 132 and/or to limit this extension to keep the thread pitch substantially constant.

Referring now to FIG. 8, free end 134 of tension element 132 includes crimped cap 145. Second spring 143 includes coils having a square transverse section. Flexible core 141 extends through first and second springs 142 and 143, and terminates close to cap 145. In one embodiment of the invention, tension element 132 further comprises third spring 146 that is coupled to flexible core 141, and first and second springs 142 and 143 at junction 147. Third spring 146 includes loop 148 at the end opposite to junction 147, which permits the tension element 132 to be fixed at first end 22 of band 20.

With respect to Fig. 9, tension element 132 is shown disposed within a skeleton 150 of the band 20. Skeleton 150 includes layer 151 that forms a distal periphery, anchor 152 that accepts loop 148 of tension element 132, and actuator housing 153. Skeleton 150 may be made of a high strength moldable plastic.

In accordance with another aspect of the invention, third spring 146 permits band 12 to be straightened for insertion through a trocar, for example a 18 mm trocar,

despite a differential elongation of the skeleton 150 and tension element 132. This feature is illustrated in FIG. 10 which shows band 12 disposed in a trocar 300 in order to facilitate laparoscopic implantation of the band 12.

Referring now to FIG. 11, in the shown embodiment, connector 30 includes housing 155 having recessed portion 156, tension element cavity 157 and cable lumen 158. Recess 156 is configured to accept actuator housing 153 of skeleton 150, so that as tension element 132 is drawn through actuator 135 it extends into tension element cavity 157. Cable lumen 158 extends through housing 155 so that cable 124 may be coupled to actuator 135. Housing 155 may be grasped in area G using atraumatic laparoscopic graspers during implantation.

In FIG. 12, actuator housing 153 of skeleton 150 is shown with actuator 135 and tension element 132 disposed therethrough. Antenna cable 17 is coupled to motor (not shown) disposed within actuator housing 153. Tension element 132 is in the fully opened (largest diameter) position, so that crimped cap 145 contacts printed circuit board 159 of the reference position switch described below with respect to FIG. 15.

With respect to FIGS. 13 and 14, actuator 135 includes motor 166 coupled to antenna cable 17 that drives nut 160 through gears 161. Nut 160 is supported by upper and lower bearings 162 to minimize energy losses due to friction. Nut 160 is self-centering, self-guiding and provides high torque-to-axial force transfer. In addition, nut 160 is self-blocking, meaning that nut 160 will not rotate due to the application of pushing or pulling forces on tension element 132. This condition may be achieved by ensuring that the height (h) of the thread divided by the circumference of

the screw ($2\pi R$) is less than the arctangent of the friction coefficient (p):

$$h/(2\pi R) < \arctan(\mu)$$

Gears 161 preferably are selected to provide good mechanical efficiency, for example, with a reduction factor greater than 1000. In addition, the volume of the actuator depicted in FIGS. 13 and 14 may be quite small, with a total volume less than 1 cm^3 and a diameter less than 12.5 mm, so that the device may easily pass through a standard trocar. In a preferred embodiment, gears 161 are selected to provide a force of more than 2 kg on the screw thread of the tension element at an electrical consumption of only 50 mW. The gears and other components of actuator 135 may be made of stainless steel or other alloys like Arcap (CuNiZn), or can be gold plated to permit operation in the high humidity likely to be encountered in a human body.

Motor 166 employed in actuator 135 may comprise a Lavet-type high precision stepper motor with a flat magnetic circuit, such as are used in watches. The motor 166 may be a two phase (two coil) motor that permits bi-directional rotation, has good efficiency, and may be supplied with a square wave signal directly by the microcontroller circuitry within antenna/controller pod 15, thus eliminating the need for an interface circuit. Alternatively, the motor employed in actuator 135 may be of a brushless DC type motor. In addition, the motor preferably is compatible with magnetic resonance imaging, i.e., remains functional when exposed to strong magnetic fields used in medical imaging equipment.

Referring now to FIG. 15, a reference position switch of an embodiment of the present invention is described. In one embodiment the actuator of the present invention employs

nut 160 driven by a stepper motor. Thus, there is no need for the system to include a position sensor or encoder to determine the length of tension element 132 drawn through the actuator. Instead, the diameter of opening 137 may be computed as a function of the screw thread pitch and the number of rotations of nut 160. At least one reference datum point may be provided which may be calculated by using a reference position switch that is activated when band 12 is moved to its fully open position. Crimped cap 145 on the free end of tension element 132 may be used to serve this function by contacting electrical traces 163 on printed circuit board 159 (and also limits elongation of the screw thread). Circuit board 159 is disposed just above bearing 165, which forms part of actuator 135. When crimped cap 145 contacts traces 163 it closes a switch that signals the implantable controller that the band 12 is in the fully open position.

Referring now to Figs. 16A and 16B, clip 30 may include a clip element 167 on first end 22 of band 20 and the housing 155 on the second end of the band 20. Clip element 167 includes aperture 170, tab 171 having hinge 172 and slot 173. Aperture 170 is dimensioned to accept housing 155 on second end 24 of band 20, while slot 173 is dimensioned to accept flange 174 disposed on second end 24.

An example of a method of coupling the first end 22 with second end 24 during implantation of the band 20 is now described. To couple first end 22 and second end 24, clip element 167 is grasped by the tab 171, and tag 18 of pod 15 (see Fig. 1) is inserted through aperture 170. Clip element 167 is then pulled towards second end 24 so that housing 155 passes through aperture 170 while housing 155 is grasped with atraumatic forceps; the conical shape of housing 155 facilitates this action. Force is applied to tab 171 until

slot 173 captures flange 174, thereby securing the first and second ends 22, 24 in the closed position. The physician may subsequently choose to disengage slot 173 from flange 174 by manipulating tab 171 using laparoscopic forceps, for example, to reposition the band 12. In some embodiments, forces inadvertently applied to tab 171 in an opposite direction will cause tab 171 to buckle at hinge 172, but will not cause flange 174 to exit slot 173. Accordingly, hinge 172 of tab 171 prevents accidental opening of clip 30 when the tab 171 is subjected to forces that cause the tab 171 to fold backwards away from housing 155 such as may arise due to movement of the patient, the organ, or bolus of fluid passing through the organ.

With respect to Figs. 17 and 18, removable tag 18 of antenna/controller pod 15 may include apertures 175. Tag 18 comprises a grip structure that facilitates manipulation and placement of the pod during implantation; after which the tag is removed, for example, using a scissors cut. Tag 18 also includes aperture 18b that allows the use of a suture thread to assist in passing the antenna/controller pod 15 behind the stomach. Holes 175 also are dimensioned to be compatible with standard suture needles from size 1-0 to 7-0 to permit pod 15 to be sutured to the patient's sternum, thereby ensuring that pod 15 remains accessible to the external antenna and cannot migrate from a desired implantation site.

As shown in FIG. 18, antenna/controller pod 15 encloses printed circuit board 176 that carries the antenna and microcontroller circuitry of band (not shown). The antenna receives energy and commands from external control 16 (see Fig. 1), and supplies those signals to the microcontroller, which in turn powers motor 166 of actuator 135 (Figs 12 and 13). The circuitry of antenna/controller pod 15 uses the

energy received from the incoming signal to power the circuit, interprets the commands received from external control 16, and supplies appropriate signals to the motor of actuator 135. The circuit also retrieves information regarding operation of the motor 166 of actuator 135 and relays that information to external control 16 via the antenna. The circuit board 176 may be covered with a water-resistant polymeric covering, e.g., Parylene, to permit use in the high (up to 100%) humidity environment encountered in the body.

Antenna/controller pod 15 may include a mechanical closure system that is augmented by silicone glue so that the pod 15 is fluid tight. This silicone glue also is used to protect soldered wires.

Actuator 135 may be linked to subcutaneous antenna/controller pod 15 to receive a radio frequency control and power signal. In one embodiment, the motor 166 of the actuator 135 has no internal energy supply, but rather is powered by the receiving circuit of the antenna through a rechargeable energy storage device, such as a capacitor. For example, the receiving circuit converts radio frequency waves received from external control 16 via the antenna into a motor control and power signal. In another embodiment the actuator 135 may be driven via an implantable rechargeable battery.

Referring to Fig. 19, one suitable arrangement of circuitry that may be employed in external control 16 of the present invention is described. External control 16 includes microprocessor 180 coupled to a keyboard/control panel 212 and display 213. External control 16 produces a signal comprising one or more data bytes to be transmitted

to the implantable antenna/controller pod (not shown) and actuator 135.

External control 16 includes modulator 181 for amplitude modulation of the RF wave from RF generator 182, which signal is emitted by an external antenna 214. The emitted wave is received by antenna 183 in the antenna/controller pod (not shown), where AM demodulator 184 extracts the data bytes from the envelope of received RF signal. The data bytes then are decoded by microcontroller 185. A special code is used that allows easy decoding of the data by microcontroller 185, but also provides maximal security against communication failure.

External oscillator 186, which is a voltage controlled oscillator (VCO), provides a clock signal to microcontroller 185. Oscillator 186 may comprise, for example, a relaxation oscillator comprising an external resistor-capacitor network connected to a discharging logic circuitry already implemented in the microcontroller or a crystal oscillator comprising a resonant circuit with a crystal, capacitors and logic circuits.

Microcontroller 185 interprets the received instructions and produces an output that drives the motor of actuator 135. As discussed above, actuator 135 may comprise a bi-directional stepper motor that drives nut 160 through a series of reducing gears. In one embodiment, the two coils of the stepper motor of actuator 135 are directly connected to microcontroller 185, which receives the working instructions from demodulator 184, interprets them and provides the voltage sequences to the motor coils. When the supply of voltage pulses to the stepper motor stops, the gears are designed to remain stationary, even if a reverse

torque or force is applied to nut 160 by tension element 132.

As also described above, use of a stepper motor in actuator 135 makes it is possible to obtain positional information on nut 160 and tension element 132 without the use of sensors or encoders, because the displacement of the tension element is proportional to the number of pulses supplied to the stepper motor coils. Two signals may be employed to ensure precise control, reference position signal S_{RP}, generated by the reference position switch of FIG. 15, and the actuator signal S_A.

According to one embodiment, signal S_A is the voltage signal taken at one of the outputs of microcontroller 185 that is connected to the motor coils of actuator 135. Alternatively, signal S_A could be derived from the current applied to a motor coil instead of the voltage, or may be an induced voltage on a secondary coil wrapped around one of the motor coils of actuator 135. In either case, signal S_A may be a pulsating signal that contains information on the number of steps turned by the rotor and further indicates whether blockage of the mechanism has occurred. Specifically, if the rotor of the stepper motor fails to turn, the magnetic circuit is disturbed, and by induction, affects signal S_A, e.g., by altering the shape of the signal. This disturbance can be detected in the external control, as described below.

Signals S_A and S_{RP} are converted into frequencies using external oscillator 186, so that the voltage level of signal S_A applied to external oscillator 186 causes the oscillator to vary its frequency F_{osc} proportionally to the signal S_A. Thus, F_{osc} contains all the information of signal S_A. When crimped cap 145 and tension element 132 are in the reference

position (band 12 is fully open), the reference position switch produces reference position signal S_{RP}. Signal S_{RP} is used to induce a constant shift of the frequency F_{OSC}, which shift is easily distinguishable from the variations due to signal S_A.

If oscillator 186 is a relaxation oscillator, as described above, signals S_A and S_{RP} modify the charging current of the external resistor capacitor network. In this case, the relaxation oscillator may comprise an external resistor-capacitor network connected to a transistor and a logic circuit implemented in microcontroller 185. With S_A and S_{RP}, the goal is to modify the charging current of the capacitor of the RC network to change the frequency of the relaxation oscillator. If the charging current is low, the voltage of the capacitor increases slowly and when the threshold of the transistor is reached, the capacitor discharges through the transistor. The frequency of the charging-discharging sequence depends on the charging current.

If oscillator 186 is a crystal oscillator, signals S_A and S_{RP} modify the capacitor of the resonant circuit. In this case, the crystal oscillator circuit preferably comprises a crystal in parallel with capacitors, so that the crystal and capacitors form a resonant circuit which oscillates at a fixed frequency. This frequency can be adjusted by changing the capacitors. If one of these capacitors is a Varicap (a type of diode), it is possible to vary its capacitance value by modifying the reverse voltage applied on it, S_A and S_{RP} can be used to modify this voltage.

In either of the foregoing cases, signals S_A and S_{RP} may be used to modify at least one parameter of a resistor-capacitor (RC) network associated with the oscillator 186 or

at least one parameter of a crystal oscillator comprising the oscillator 186.

Referring still to FIG. 19, signals S_A and S_{RP}, derived from the stepper motor or from the output of the microcontroller 185, may be used directly for frequency modulation by the oscillator 186 without any encoding or intervention by the microcontroller 185. By using oscillator 186 of microcontroller 185 as part of the VCO for the feedback signal, no additional components are required, and operation of micro controller 185 is not adversely affected by the changes in the oscillator frequency F_{OSC}. The oscillating signal F_{OSC} drives voltage driven switch 187 for absorption modulation, such that feedback transmission is performed with passive telemetry by FM-AM absorption modulation.

More specifically, signal F_{OSC} drives switch 187 such that during the ON state of the switch 187 there is an increase in energy absorption by RF-DC converter 188. Accordingly, therefore the absorption rate is modulated at the frequency F_{OSC} and thus the frequency of the amplitude modulation of the reflected wave detected by external control 16 contains the information for signal S_A. As discussed below, pickup 189 in external control 16 separates the reflected wave where it can be decoded by FM demodulation in demodulator 190 to obtain signal $S_{A'}$. This method therefore allows the transmission of different signals carried at different frequencies, and has the advantage that the ON state of switch 187 can be very short and the absorption very strong without inducing an increase in average consumption. In this way, feedback transmission is less sensitive to variation in the quality of coupling between the antennas 183 and 214.

In external control 16, the feedback signal F_{OSC} is detected by the pickup 189 and fed to FM demodulator 190, which produces a voltage output V_{OUT} that is proportional to F_{OSC}. V_{OUT} is fed to filter 191 and level detector 192 to obtain the information corresponding to the actuator signal S_A, which in turn corresponds to the pulses applied to the stepper motor coil. Microprocessor 180 counts these pulses to calculate the corresponding displacement of the tension element 32, which is proportional to the number of pulses.

Signal V_{OUT} also is passed through analog-to-digital converter 193 and the digital output is fed to the microprocessor 180, where signal processing is performed to detect perturbations of the shape of the feedback signal that would indicate a blockage of the rotor of the stepper motor. Microprocessor 180 stops counting any detected motor pulses when it detects that the actuator is blocked, and outputs an indication of this status. Level detector 194 produces an output when it detects that the demodulated signal V_{OUT} indicates the presence of the reference position signal S_{RP} due to activation of the reference position switch. This output induces a reset of the position of the tension element calculated by microprocessor 180 in the external control. In this way, a small imprecision, e.g. an offset, can be corrected.

As described above, external control 16 may be configured to transmit both energy and commands to the implantable controller circuitry in antenna/controller pod 15. External control 16 may also receive feedback information from the implantable controller that can be correlated to the position of the tension element and the diameter of the loop. As will be apparent to one of skill in the art, external control 16 and the implantable controller may be configured in a master-slave arrangement, in which

the implantable controller is completely passive, awaiting both instructions and power from external control 16.

Power may be delivered to the implantable pod 15 via magnetic induction. The quality of the coupling may be evaluated by analyzing the level of the feedback signal received by external control 16, and a metric corresponding to this parameter may be displayed on signal strength indicator 217 on control 16, which in the shown embodiment, includes 6 LEDs (corresponding to six levels of coupling). If the coupling between the antennae is insufficient, the motor of actuator may not work properly.

Referring now to FIG. 21, band 20 of the presently described system of the invention is shown implanted in a patient. Band 20 of band 12 is disposed encircling the upper portion of the patient's stomach S while antenna/controller pod 15 is disposed adjacent to the patient's sternum ST. Pod 15 is located in this position beneath the patient's skin SK so that it is easily accessible in the patient's chest area to facilitate coupling of the implanted pod 15 to an external antenna of control 16.

Referring to FIGS. 22A to 22H, a method of implanting the band and pod of the system of the present invention is described. The method is similar to laparoscopic procedures used to implant previously-known hydraulically-actuated gastric bands.

Access to the abdomen is obtained by using 4 to 6 small holes, generally 10 to 18 mm in diameter, with a trocar inserted in each hole, as depicted in FIG. 22A. A camera and laparoscopic surgical tools are introduced and manipulated through the trocars. In addition, to permit free

motion of the surgical tools and camera, the abdomen is inflated with CO_2 to an overpressure of approximately 0.15 bars.

In Figs. 22B-22E, the band 20 of the adjustable portion 12 is straightened (as depicted in FIG. 10) and inserted, antenna first, into the abdomen through an 18 mm trocar. Alternatively, a laparoscopic cannula may be used to make an incision and then withdrawn, and the device inserted through the opening so created (other instruments also may be used to form this laparotomy). In Fig. 22B, tag 18 of antenna/controller pod 15 is shown entering the abdomen through trocar 300 using atraumatic graspers 310. In Fig. 22C, housing 155 is shown being drawn into the abdomen through trocar 300, again using atraumatic graspers 310. Fig. 22D shows band 20 entering the abdomen in an extended position. In Fig. 22E, the band 20 is permitted to resume its arcuate shape.

Band 20 then is manipulated using atraumatic graspers 310 as described elsewhere herein, to secure the band 20 around the upper portion of the patient's stomach until slot 173 of clip 30 is engaged with flange 174, as shown in Fig. 22F. A fold of stomach tissue then may be sutured around the band 20 to prevent migration of the band 20.

Finally, as shown in Fig. 22G, a channel may be formed through the abdominal wall and antenna/controller pod 15 passed through the channel. Tag 18 then is cut off of antenna/controller pod 15, and the pod 15 is sutured into position above the patient's sternum, as depicted in Fig. 22H. The trocars then are removed, and the band 20 may be activated to adjust the diameter of the inner diameter as desired by the physician.

The process of removing the band 20 of the present invention involves substantially reversing the sequence of steps described above, and may be accomplished non-destructively. In particular, a plurality of cannulae into the abdominal cavity and the abdominal cavity then insufflated to create a pneumoperitoneum. Using laparoscopic graspers, the clip 30 may be unclipped and the band 20 removed from a position encircling the patient's stomach. The band 20 may then be straightened and withdrawn from the abdominal cavity either through one of the plurality of cannulae or via a laparotomy.

Figs. 23 through 25 illustrate an alternative contact region 1010 of a gastric banding system of the present invention. Contact region 1010 may be identical to contact region 44 except as explicitly described below. Contact region 1010 can replace contact region 44 described and shown, for example, in Figs. 3 and 3A, in system 10.

Contact region 1010 comprises a membrane 1014 which may be substantially identical to membrane 45 described and shown elsewhere herein. In this embodiment however, cushion segments 1016, which may be made of the same incompressible materials as cushion segments 60, are affixed to an external surface of the membrane 1014 and define at least a portion of the stomach-facing surface of the contact region 1010. The cushion segments 1016 may be individually molded to, or molded as a whole, directly to the membrane 1014 using conventional molding techniques, for example, conventional overmolding techniques.

In a specific embodiment, cushions 1016 are made of silicone elastomer having a hardness of 10 Shore A and membrane 1014 is made of silicone elastomer having a hardness of 30 Shore A.

Alternatively, the membrane 1014 may be made of silicone elastomer of different hardness, such as, for example, 20 Shore A to 45 Shore A. Alternatively still, the cushions could be made of an even softer silicone elastomer, such as 5 Shore A or 1 Shore A. Alternatively, the cushions or the membrane could be made of other suitable implantable materials.

Figs. 24 and 25 are cross sectional views of the contact region shown in Fig. 23 taken along line 24-24 and line 25-25, respectively.

Another feature of this embodiment of the invention is shown in Fig 24. Specifically, the membrane 1014 may includes a structural support, for example, a wedge 1025 located at the interface between the membrane 1014 and each of the cushion segments 1016. Wedges 1025 may provide an increased surface area on which the cushion segments are molded thereby providing additional adherence and/or support between the membrane 1014 and the cushion segments 1016. Like membrane 45, membrane 1014 includes corrugations 1027 for facilitating unfolding or expansion of the membrane 1014 during adjustment of the band.

Another advantageous feature of this embodiment is shown in Figs. 26-27A. In some embodiments, the cushion segments 60 and tension segments 52 form an inner circumference of the loop configuration having a generally star-shape, defined by the contact region, as shown in Fig. 26. The stomach lumen is indicated by numeral 1033. During constriction of the band, which is shown dilated in Figs. 26 and 26A and constricted in Figs 27 and 27A, adjacent incompressible cushion segments 60 form, a progressively narrowing angle, for example, a progressively narrowing

substantially V-shaped surface having convex, arcuate surfaces defined by the cushion segments 60. Tension segments 52 located between the adjacent cushion segments 60 and form the vertices of the angles.

While not wishing to be bound by any particular theory of operation, it is believed that the structure of the contact member 44 and at least partially due to the incompressibility of the cushion segments 60 enables the band to constrict about the stomach without pinching the tissue. For example, as shown in Fig 27 and 27A, the stomach tissue does not become entrapped between adjacent cushion segments 60. During constriction of the band, the convex stomach-facing surfaces maintain their shape and form no gaps, while folding inwardly toward one another. This mechanism and structure causes the tissues of the stomach constricted without the tissues becoming entrapped and/or pinched. This progressive V-shape acts differently than a mechanical pliers.

As stated elsewhere herein, the system of the present invention has numerous applications apart from gastric banding. For example, the system of the present invention may be used for the treatment of fecal incontinence, ileostomy, coleostomy, gastro-esophageal reflux disease, urinary incontinence and isolated-organ perfusion.

For treatment of fecal incontinence, the ring may be used with little or no modifications. In addition, because the ring adjustment procedure will be performed by the patient on at least a daily basis, a portable user-friendly external control may be used. In addition, because the ring will regularly be transitioned between the closed and fully opened position, the patient microchip card is unneeded. Instead, the fully closed position may be stored in the

memory of the implantable controller, and read by the external remote at each use (subject to periodic change by the physician).

A similarly modified device could be used by patients who have undergone ileostomy or coleostomy, or disposed surrounding the esophageal junction, to treat gastro-esophageal reflux disease.

For treatment of urinary incontinence, the system of the present invention may be further modified to minimize the volume of the loop surrounding the urethra by moving the actuator motor to a location elsewhere in the lower abdomen or pelvis, and coupling the actuator to the motor via a transmission cable.

The present invention also may be beneficially employed to perform isolated-organ perfusion. The treatment of certain cancers requires exposure to levels of chemotherapy agents that are too high for systemic circulation. It has been suggested that one solution to this problem is perform an open surgery procedure in which blood flow to the cancerous organ is stopped and quiescent blood replaced by circulation from an external source containing a desired dose of drug. Individual or multiple rings of the present invention may be used as valves to isolate the cancerous organ and permit perfusion of the organ with high doses of drugs. Such procedures could thus be performed on a repetitive basis without surgery, thereby reducing the trauma and the risk to the patient while improving patient outcomes.

Although particular embodiments of the present invention have been described above in detail, it will be understood that this description is merely for purposes of

illustration. Further variations will be apparent to one skilled in the art in light of this disclosure and are intended to fall within the scope of the appended claims.

What is claimed is:

1. A system for regulating an organ or duct, comprising:

a band having a first end, a second end, a distal region and a proximal region and a connector configured to couple the first end with the second end such that the band is formable into a loop configuration structured to circumscribe an organ or duct;

a membrane disposed between the first end and the second end of the band;

at least one cushion segment coupled to the membrane and disposed on the proximal region of the band; and

a mechanism for enabling adjustment of an inner circumference of the loop configuration.

2. The system of claim 1 wherein the at least one cushion segment comprises a plurality of cushion segments disposed on the proximal region.

3. The system of claim 2 further wherein the membrane defines a plurality of tension segments disposed in a substantially alternating manner between adjacent cushion segments.

4. The system of claim 1 wherein the at least one cushion segment is made of a substantially incompressible material.

5. The system of claim 1 wherein the at least one cushion segment is made of an incompressible material.

6. The system of claim 1 wherein the at least one cushion segment comprises a single incompressible cushion segment disposed along substantially the entire proximal region.

7. The system of claim 6 wherein the substantially continuous cushion segment includes thick regions and relatively thin regions disposed in a substantially alternating manner between the thick regions.

8. The system of claim 1 wherein the at least one cushion member is located on an external surface of the membrane.

9. The system of claim 1 wherein the at least one cushion segment is molded to the membrane.

10. The system of claim 1 wherein the at least one cushion segment is molded to an external surface of the membrane.

11. The system of claim 1 wherein the at least one cushion segment defines at least a portion of the inner circumferential surface of the band when the band is in the loop configuration.

12. The system of claim 1 wherein the at least one cushion segment is substantially incompressible.

13. The system of claim 1 wherein the membrane includes at least one support wedge secured to the at least one cushion segment.

14. The system of claim 1 wherein the membrane includes corrugated surfaces to allow unfolding of the membrane during adjustment.

15. The system of claim 1 wherein the membrane is made of a first material and the at least one cushion segment is made of a second material having a different durometer than the first material.

16. The system of claim 1 wherein the at least one cushion segment is located on an internal surface of the membrane.

17. The system of claim 1 wherein the mechanism comprises an interface connected to the band, and a control capable of communicating with the interface to regulate constriction of the band about said organ or duct.

18. A system for regulating an organ or duct, comprising:

a band having a first end, a second end, a distal region and a proximal region and a connector configured to couple the first end with the second end such that the band is formable into a loop configuration structured to circumscribe an organ or duct;

a contact region disposed between the first end and the second end of the band;

the inner circumference of the loop configuration having a generally star-shape defined by the contact region; and

a mechanism for enabling adjustment of the inner circumference of the loop configuration.

19. The system of claim 18 wherein the contact region includes a plurality of cushion segments spaced apart by a plurality of tension segments.

20. The system of claim 19 wherein the plurality of tension segments define vertices of the generally star-shape.

21. The system of claim 18 wherein the contact region is structured to prevent pinching of the organ when the band is positioned around the organ and the inner circumference is adjusted.

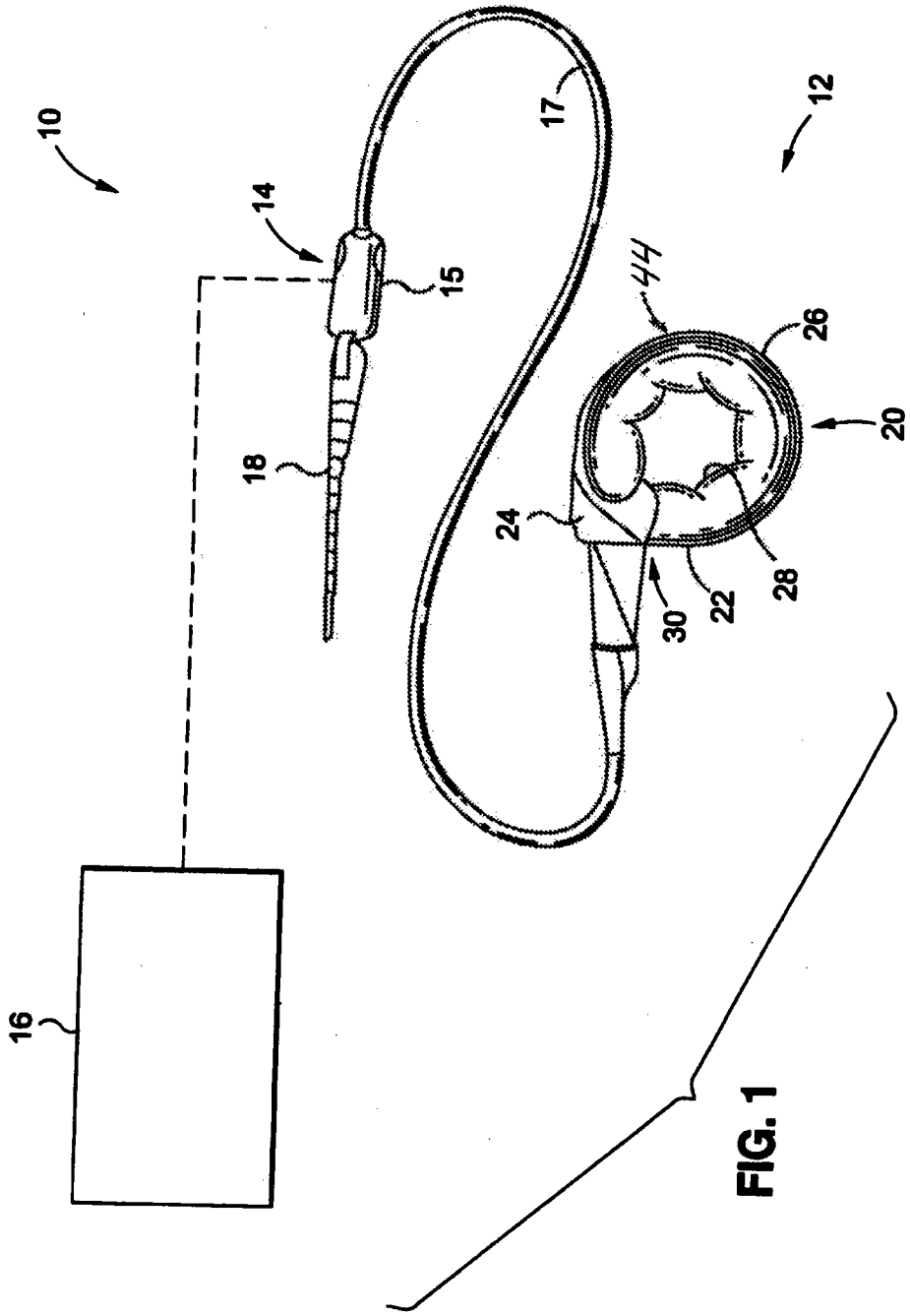


FIG. 1

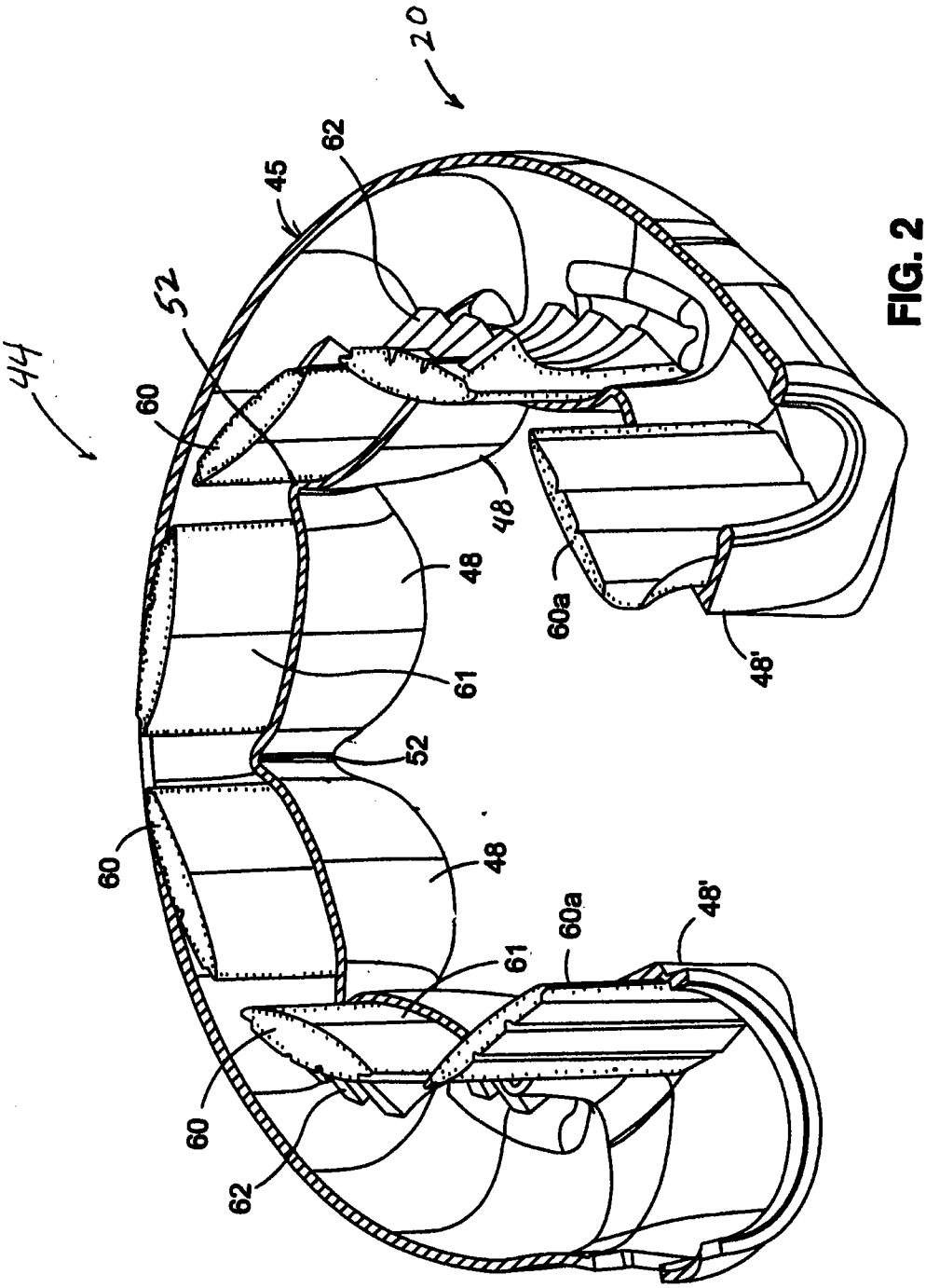


FIG. 2

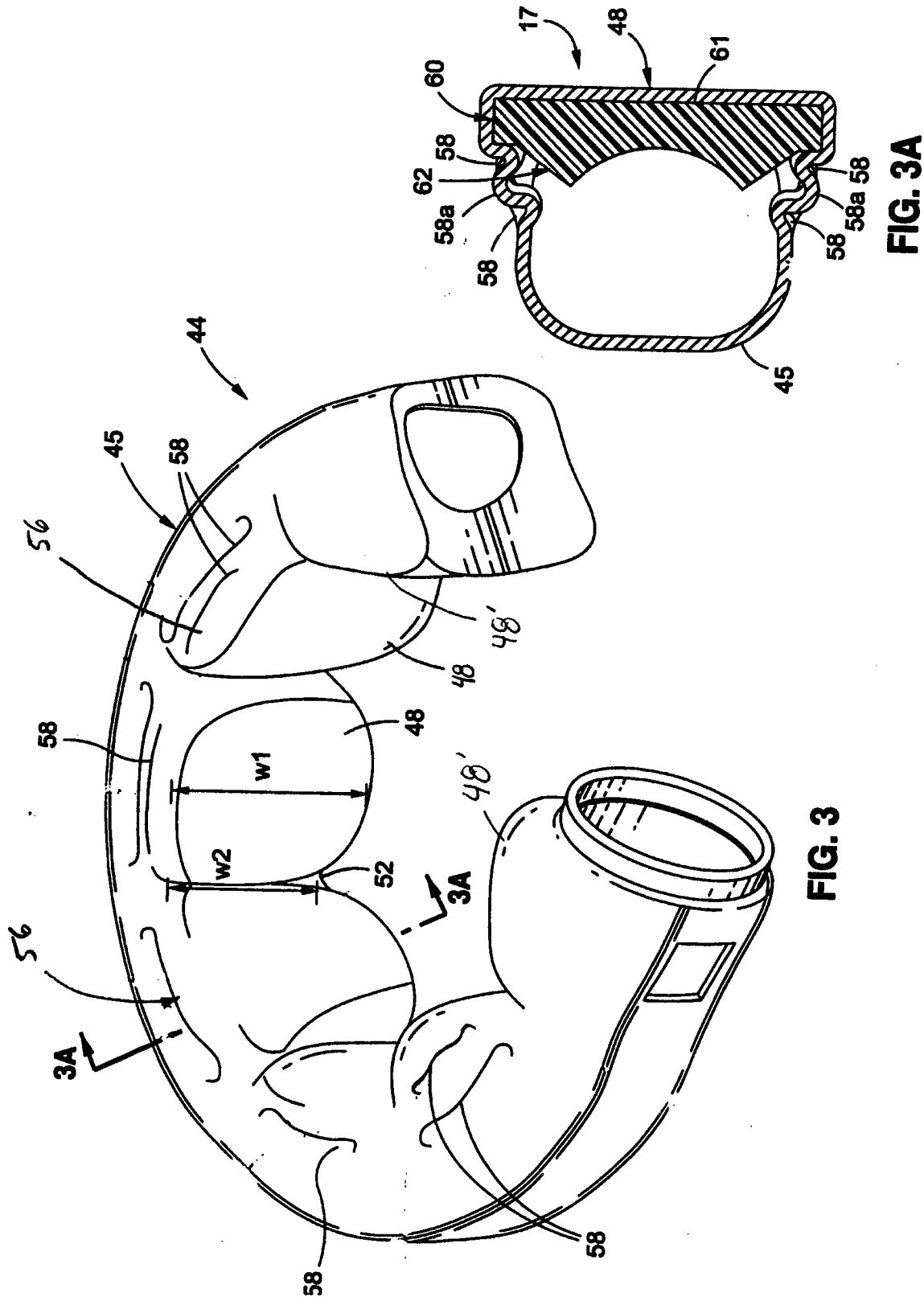

17
48
61
60
58
62
58a
58
58
58a
58
58
45
44
45
58
56
48'
48
58
48
w1
w2
52
3A
48'
56
3A
58
58
58

FIG. 3A

FIG. 3

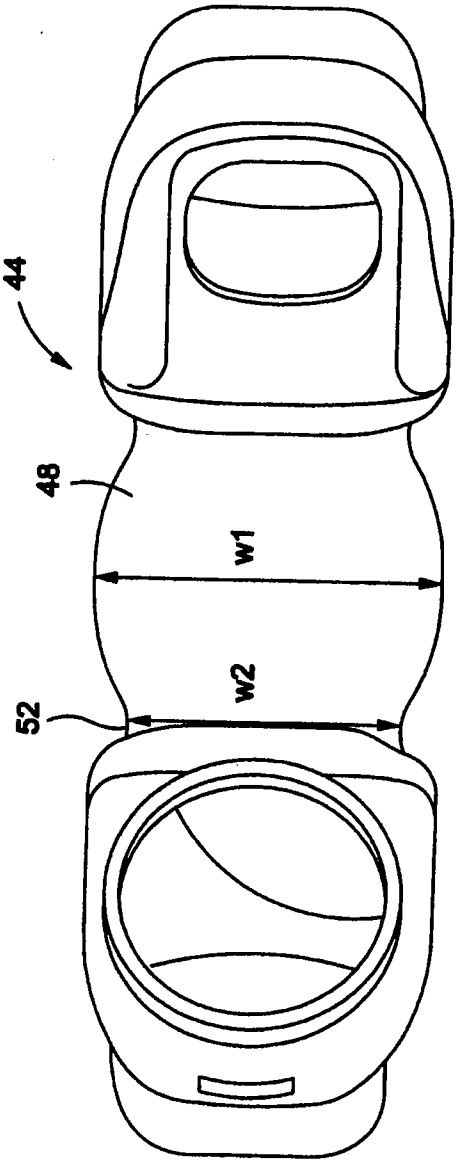


FIG. 4A

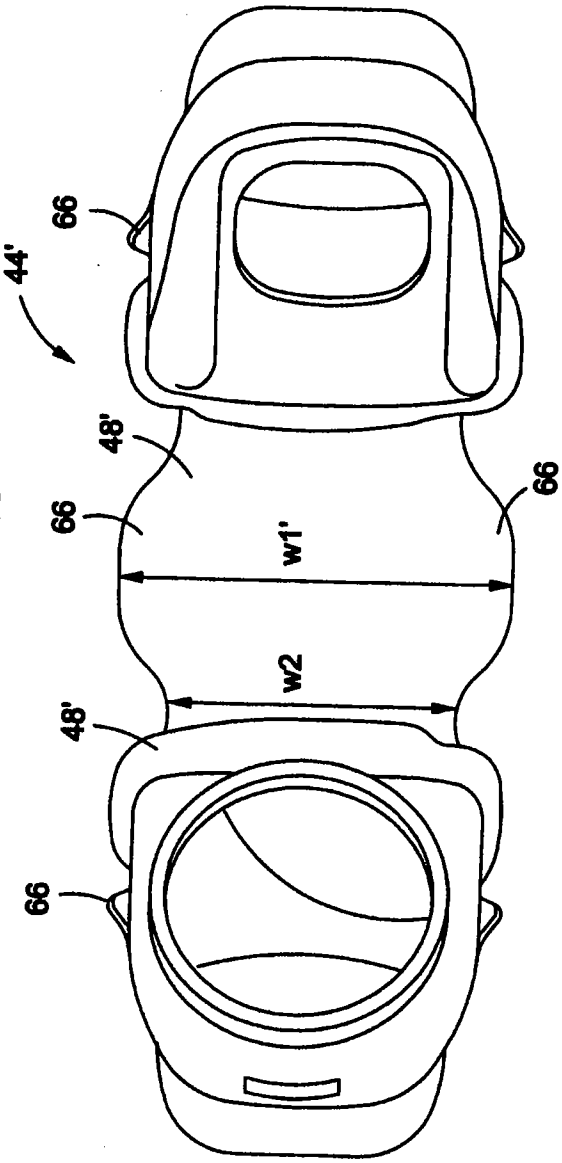


FIG. 4B

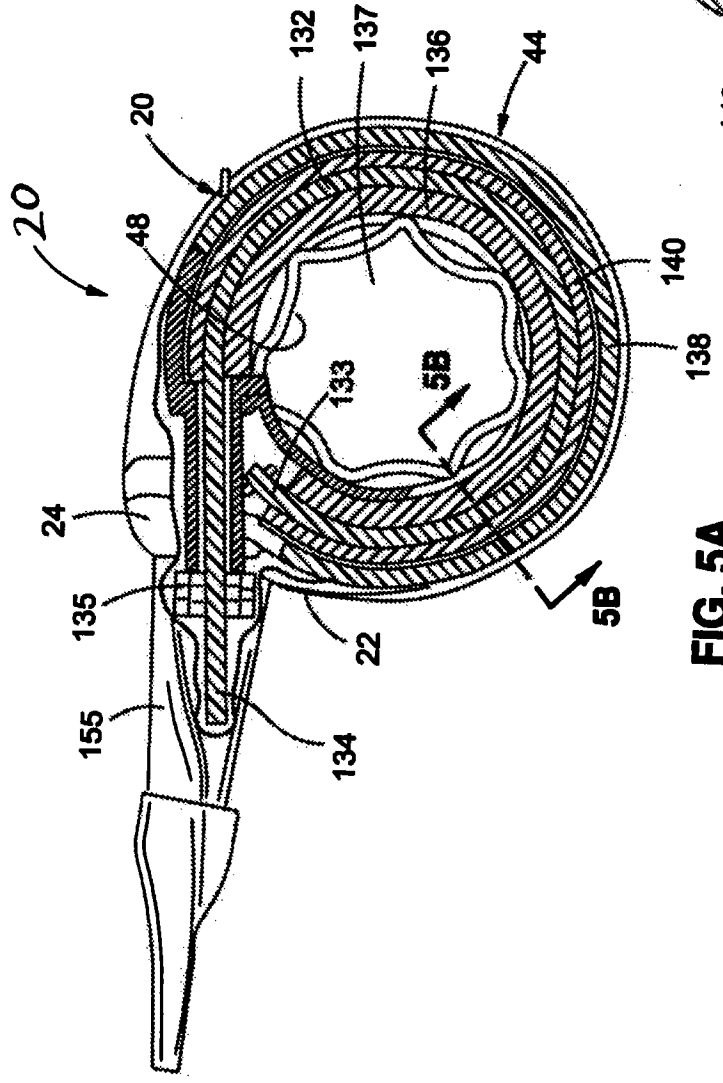
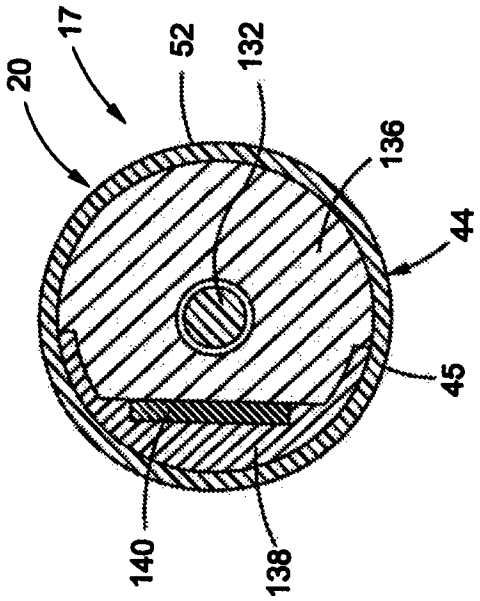

20
48
20
132
137
136
44
140
138
133
5B
24
135
22
155
134
5B

FIG. 5A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52
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136
44
45
140
138

FIG. 5B

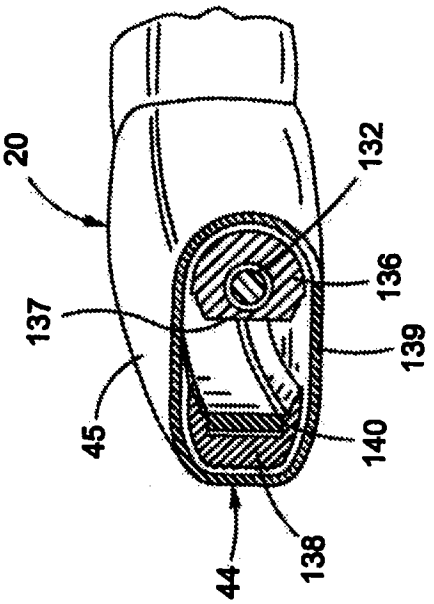
20
132
136
137
139
45
140
44
138

FIG. 5D

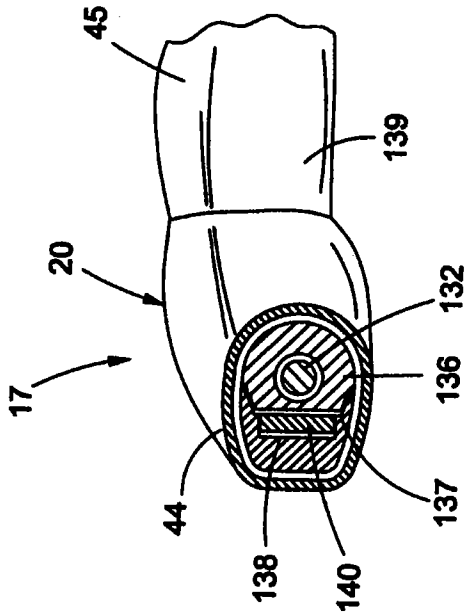
45
139
20
132
17
136
44
137
138
140

FIG. 5C

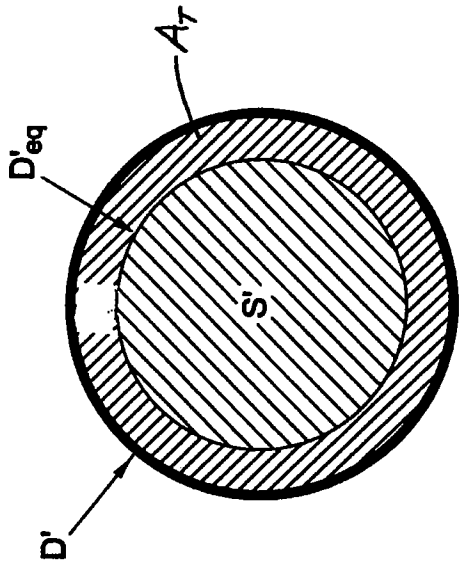

FIG. 5F

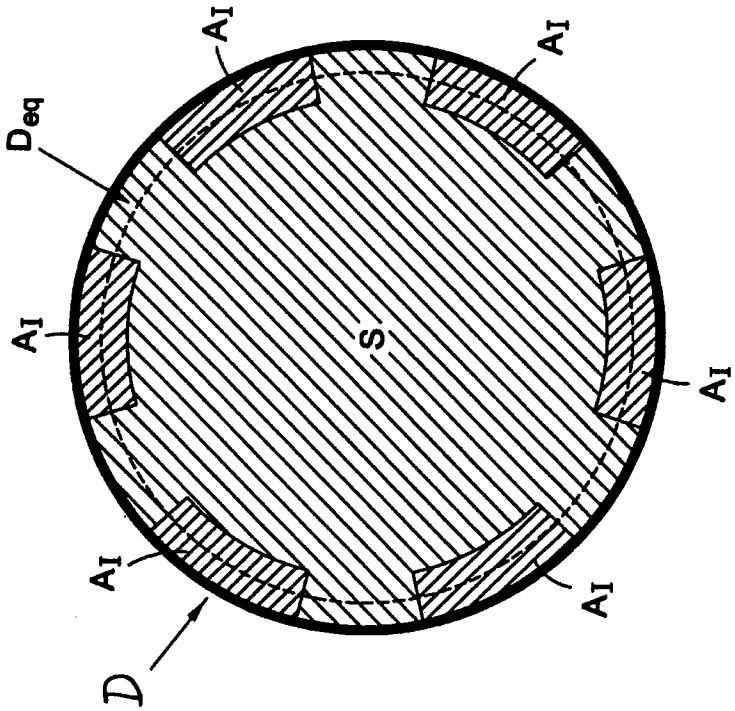

FIG. 5E

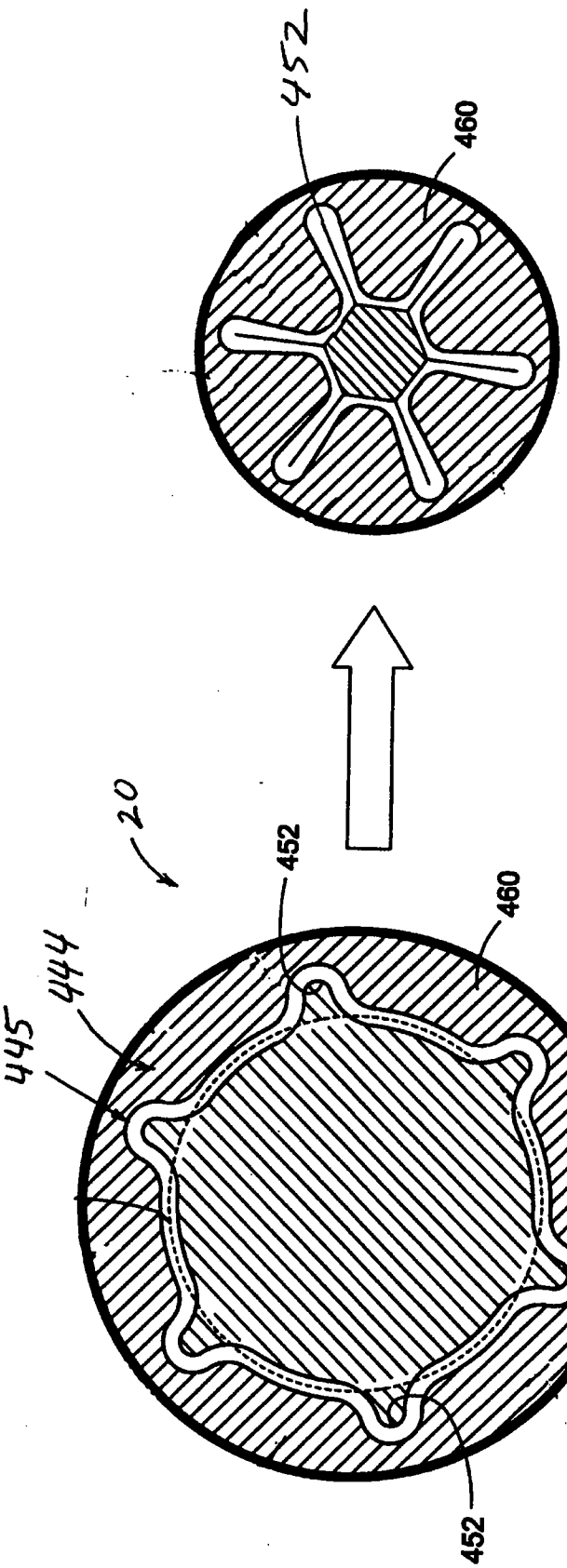

FIG. 5H

FIG. 5G

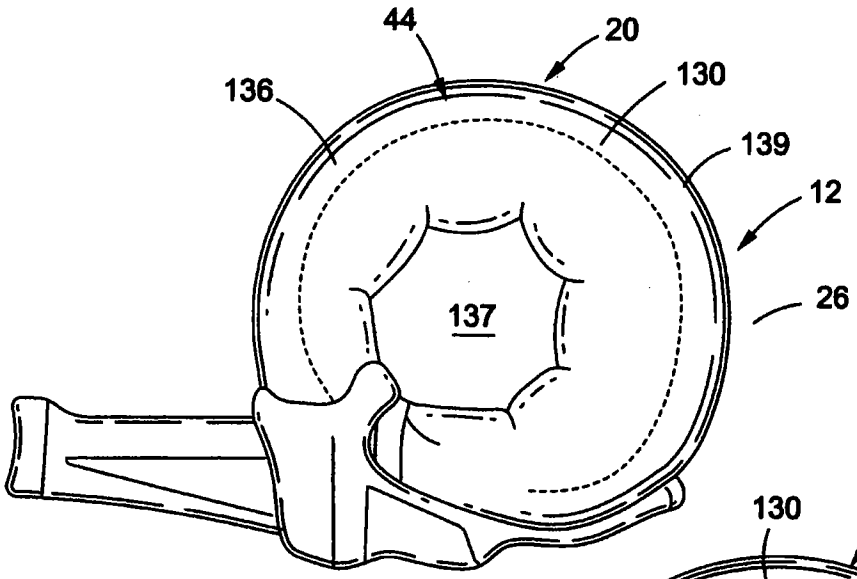

FIG. 6A

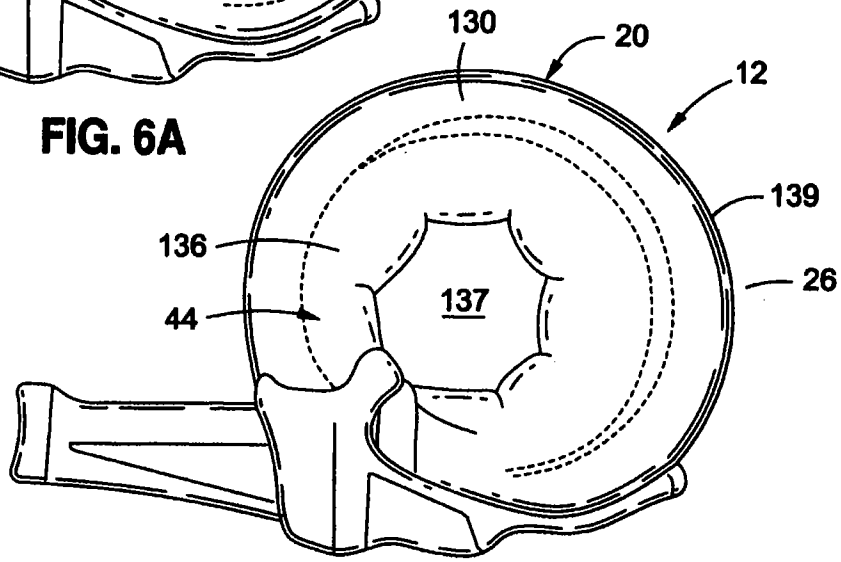

FIG. 6B

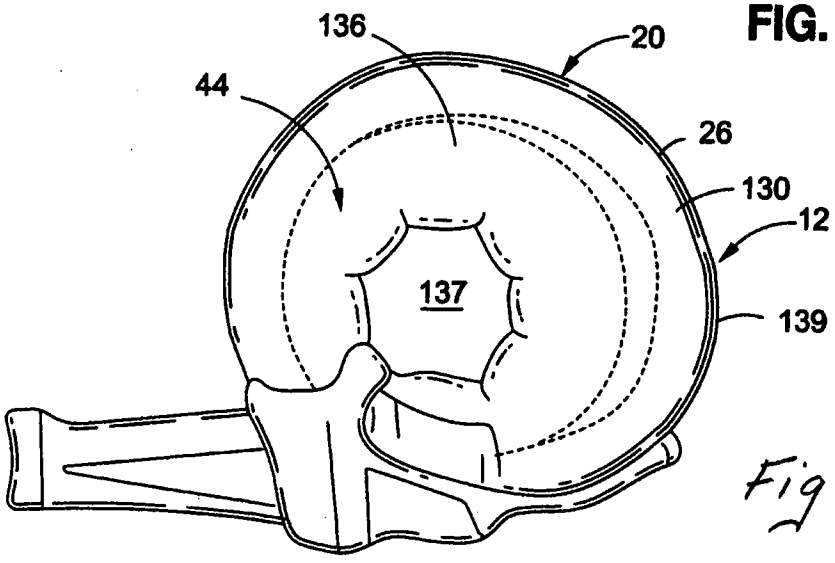

Fig 6C

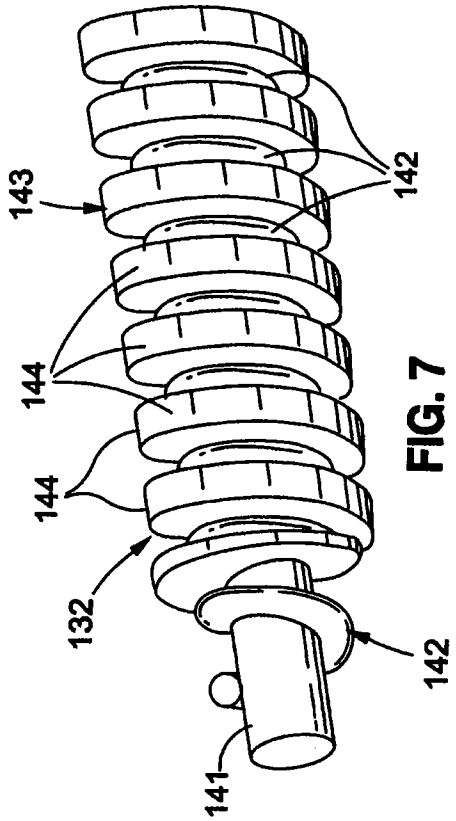

FIG. 7

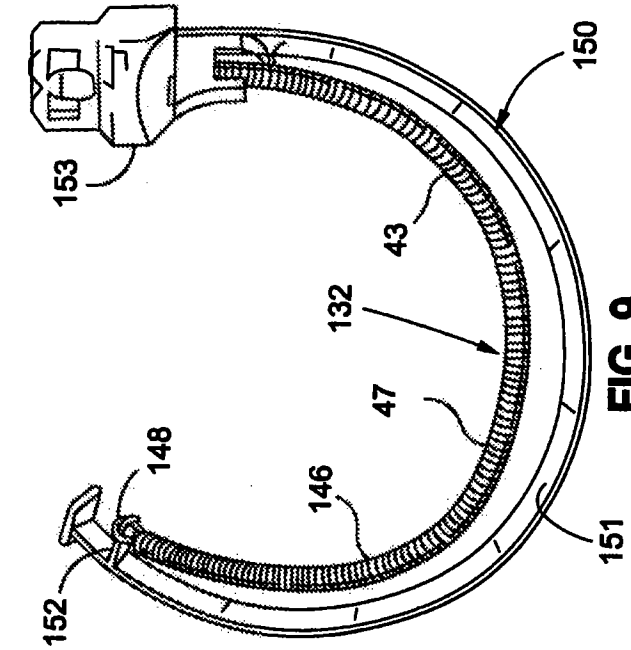

FIG. 9

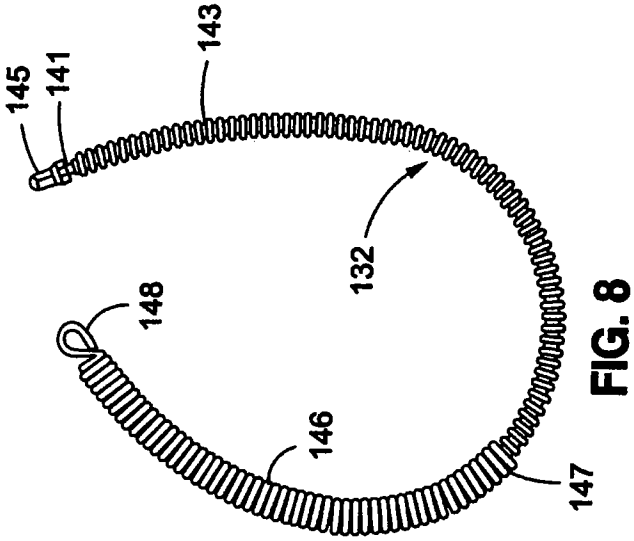

FIG. 8

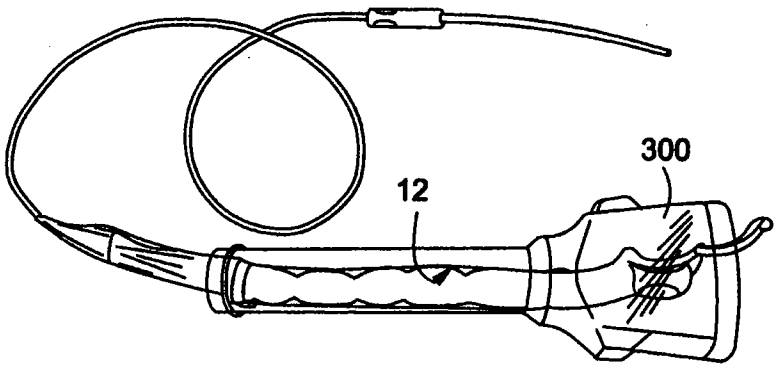

FIG. 10

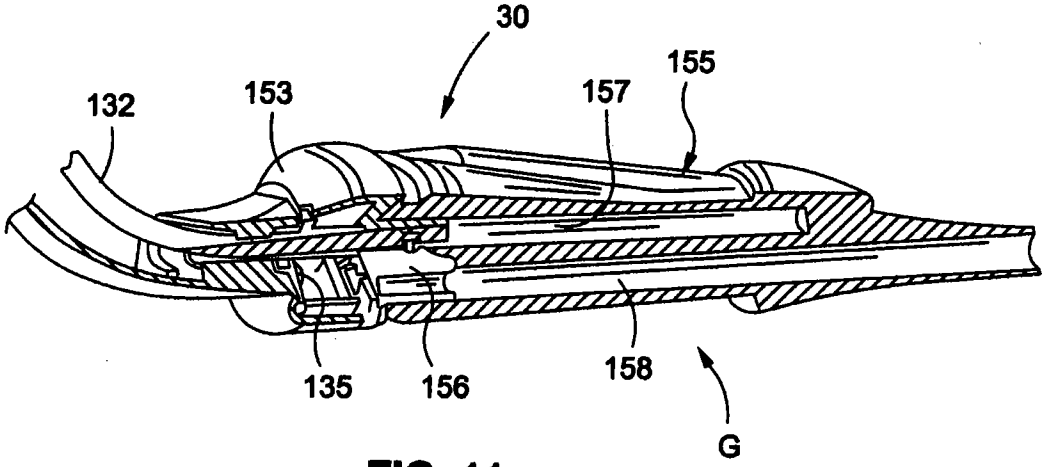

FIG. 11

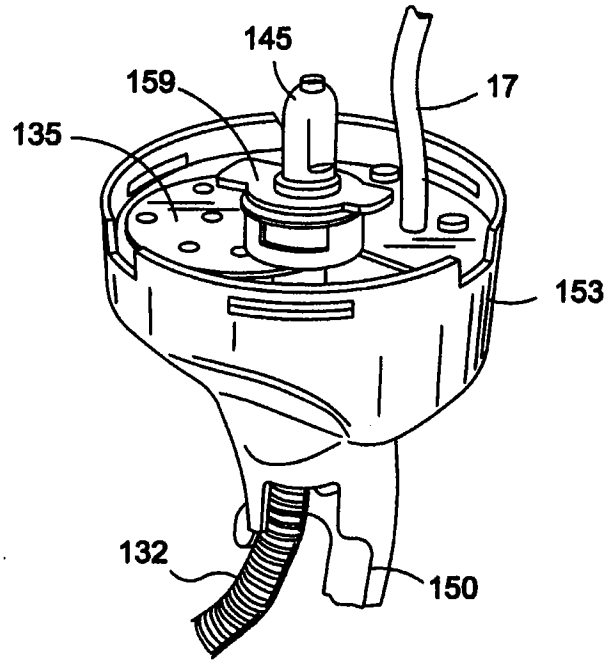

FIG. 12

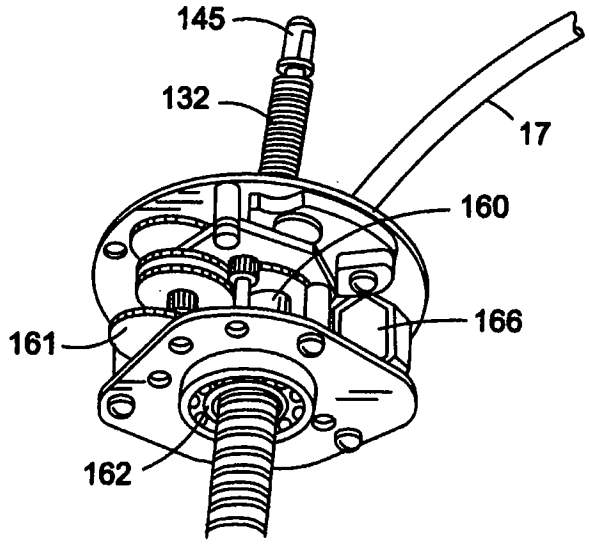

FIG. 13

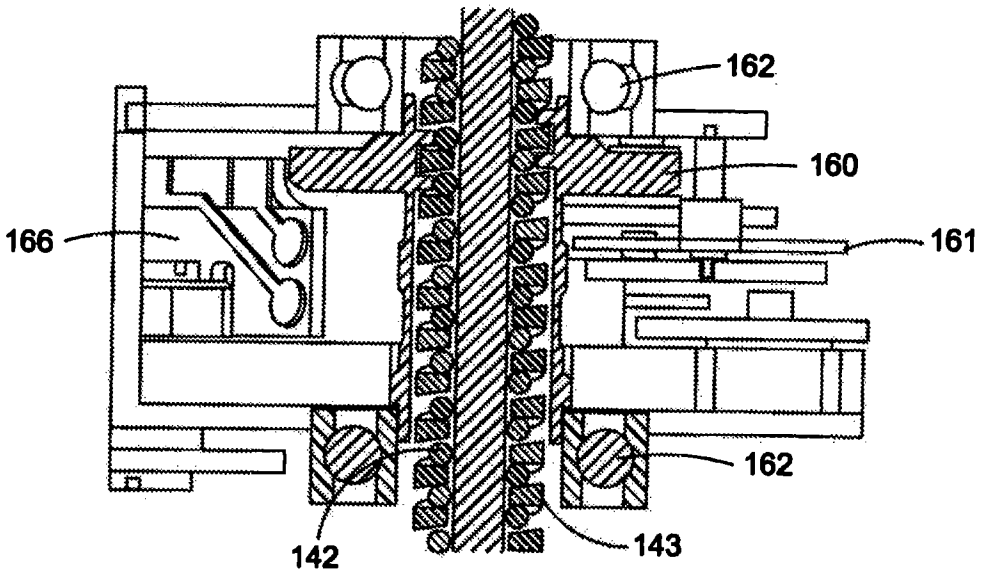

FIG. 14

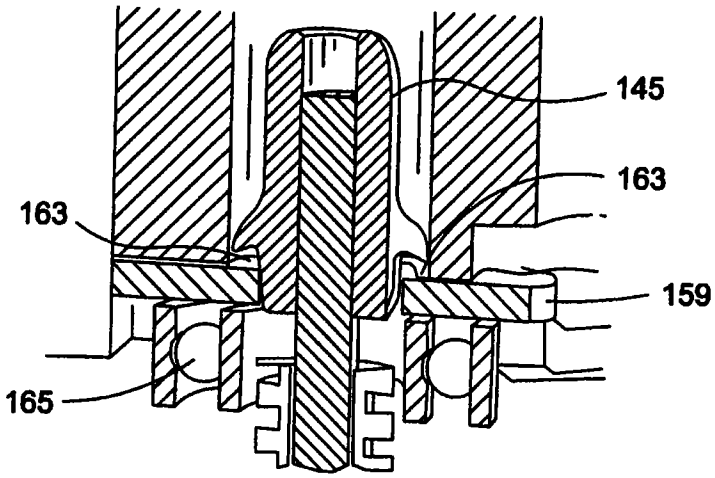

FIG. 15

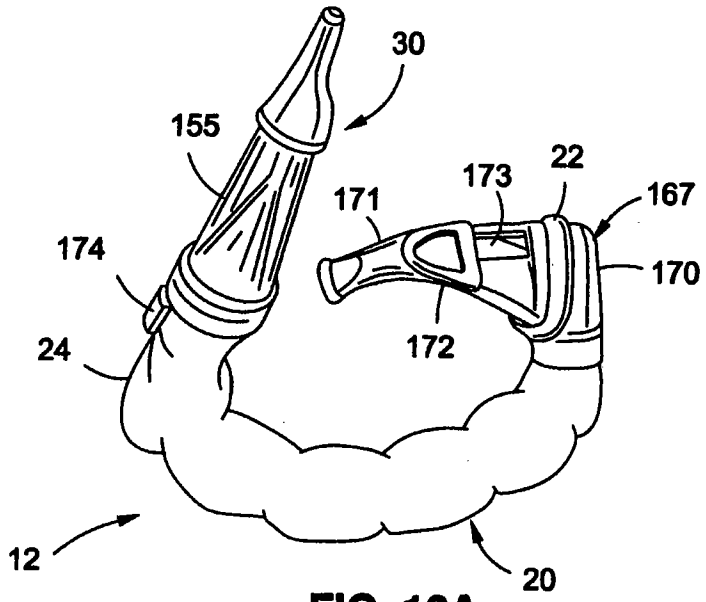

FIG. 16A

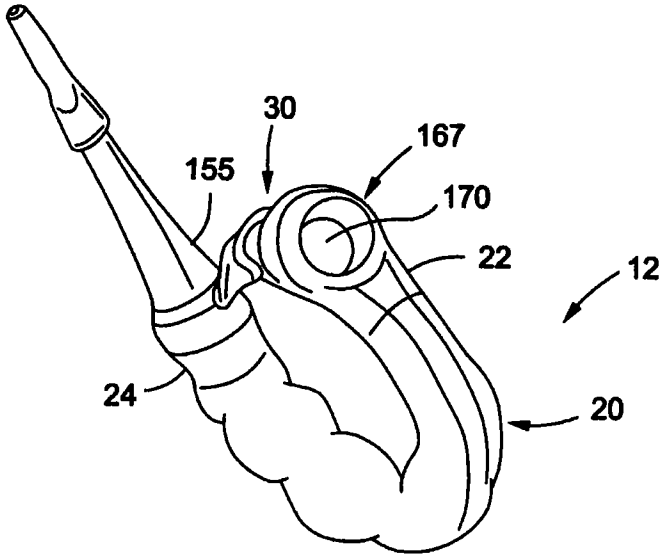

FIG. 16B

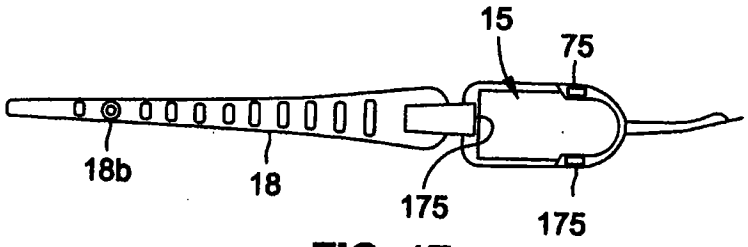

FIG. 17

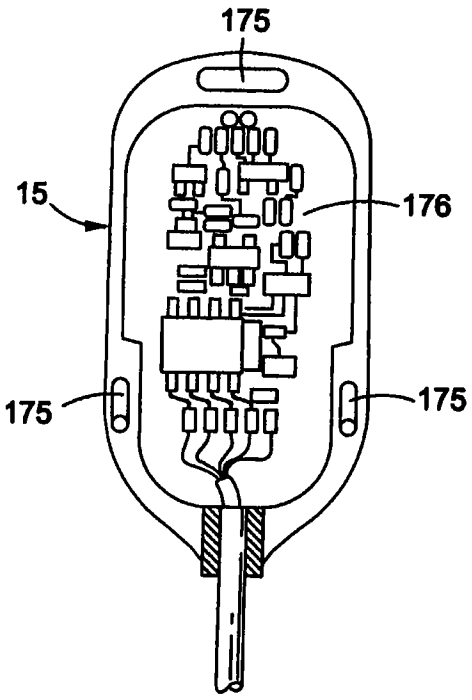

FIG. 18

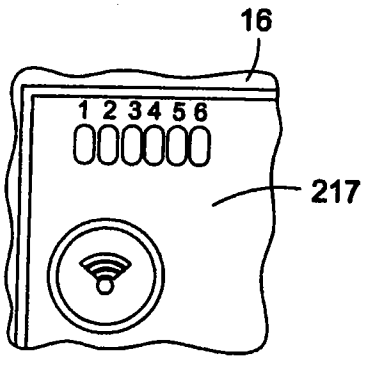

FIG. 20

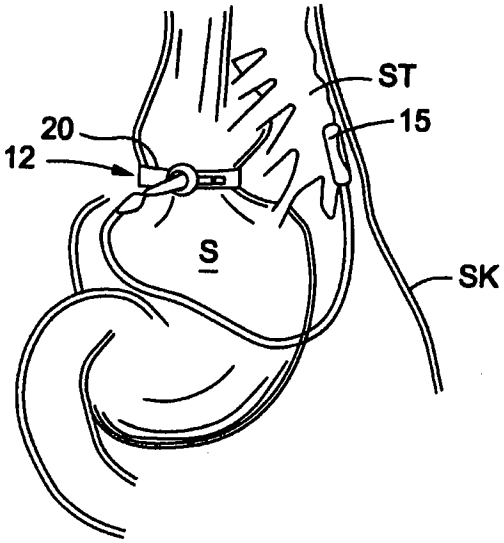

FIG. 21

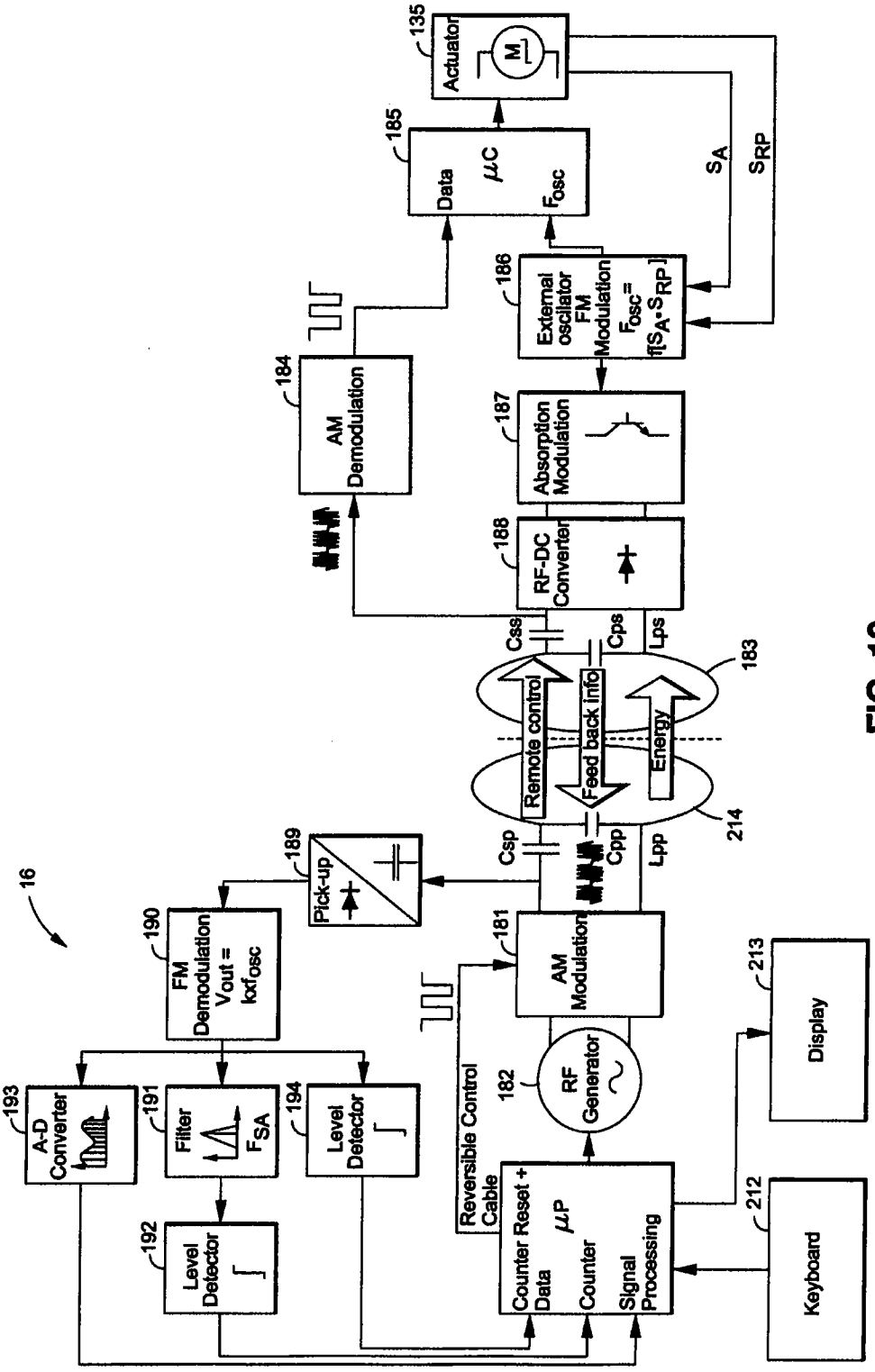
16
135
Actuator
M
185
Data
μC
Fosc
SA
SRP
186
External oscillator FM Modulation
Fosc= f[SA•SRP]
184
AM Demodulation
187
Absorption Modulation
188
RF-DC Converter
Css
Cps
Lps
183
Remote control
Feed back info
Energy
214
189
Pick-up
Csp
Cpp
Lpp
190
FM Demodulation
Vout = kxfosc
181
AM Modulation
213
Display
193
A-D Converter
191
Filter
FSA
194
Level Detector
182
RF Generator
Reversible Control Cable
192
Level Detector
Counter Reset + Data
μP
Counter
Signal Processing
212
Keyboard

FIG. 19

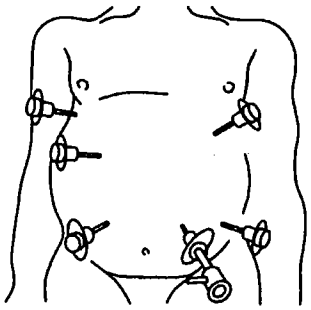

FIG. 22A

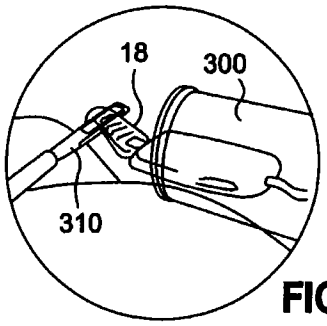

FIG. 22B

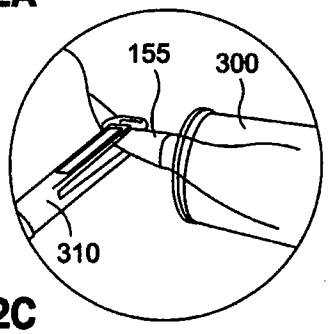

FIG. 22C

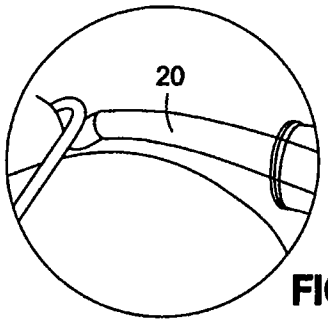

FIG. 22D

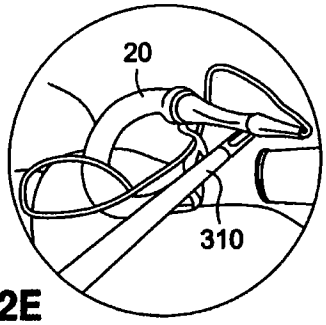

FIG. 22E

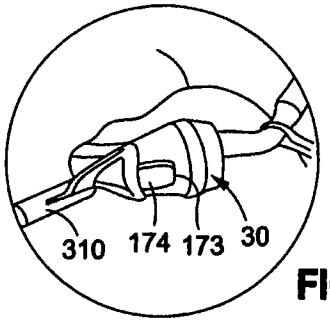

FIG. 22F

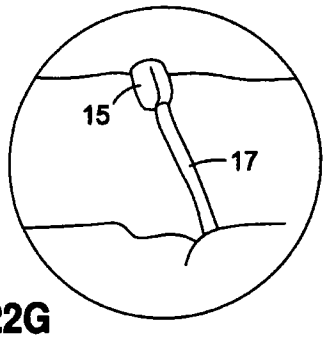

FIG. 22G

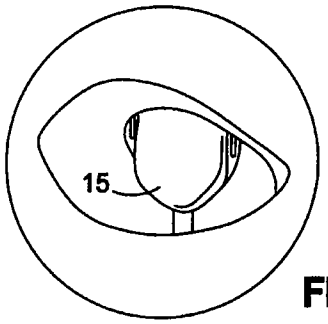

FIG. 22H

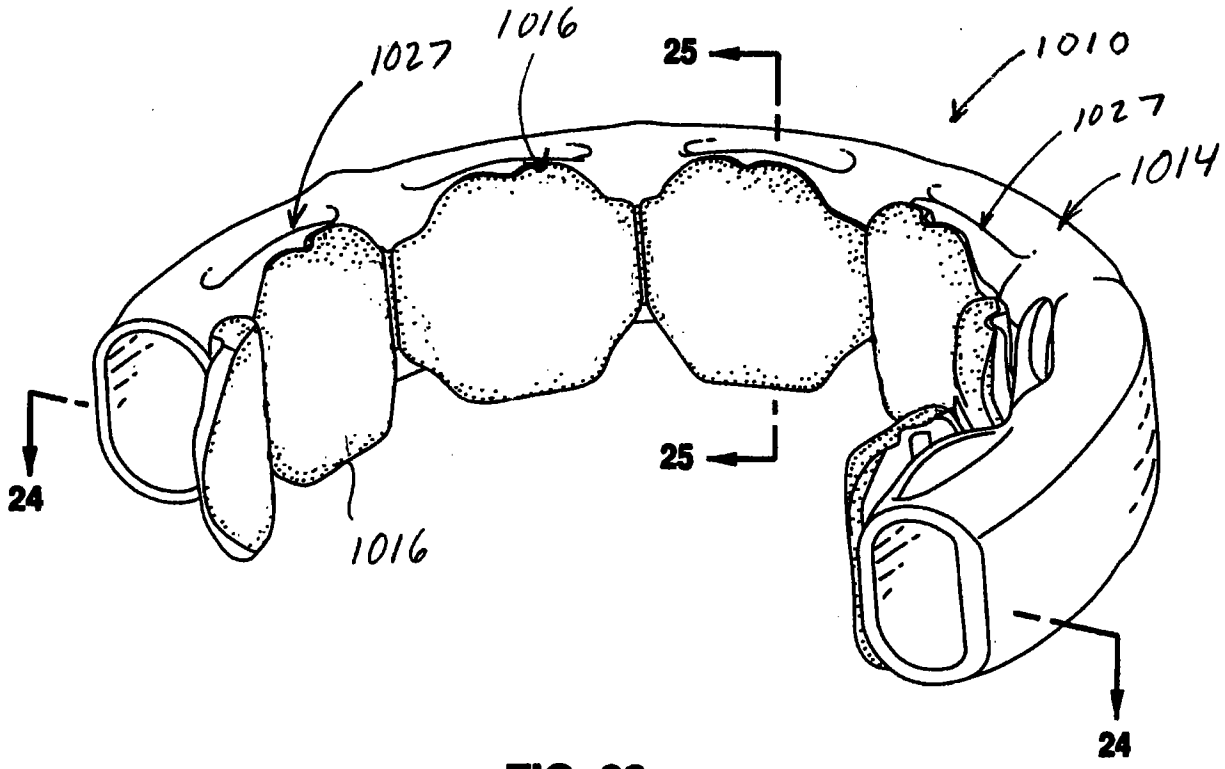

FIG. 23

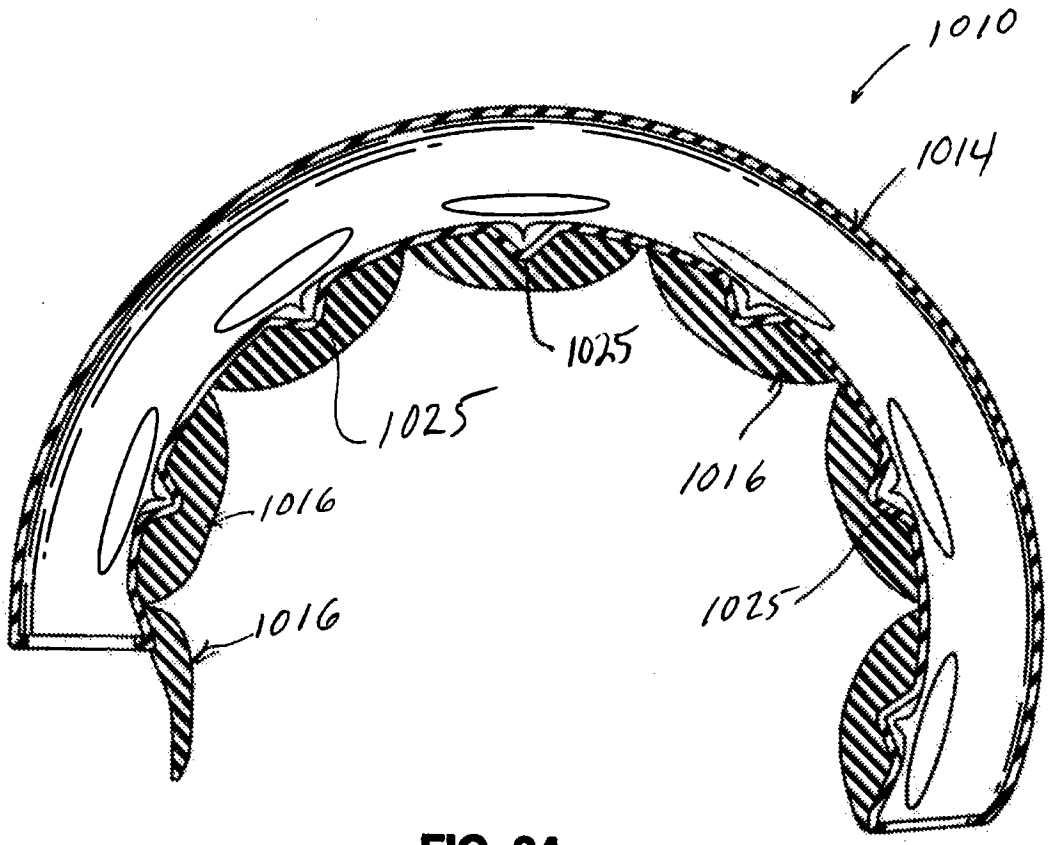
1010
1014
1025
1025
1016
1016
1016
1025

FIG. 24

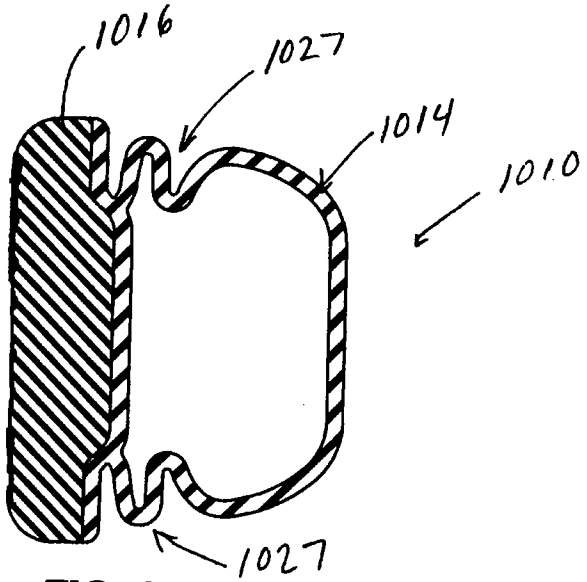
1016
1027
1014
1010
1027

FIG. 25

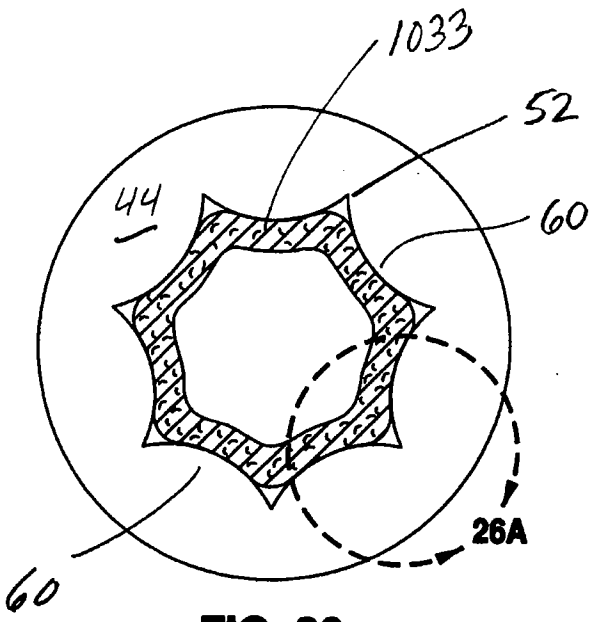

FIG. 26

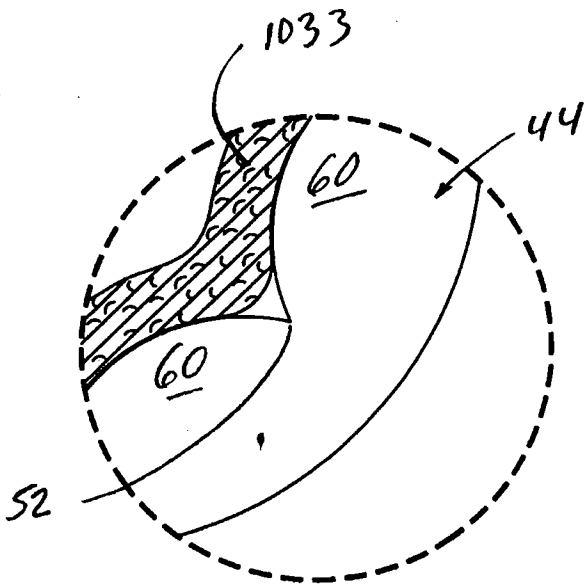

FIG. 26A

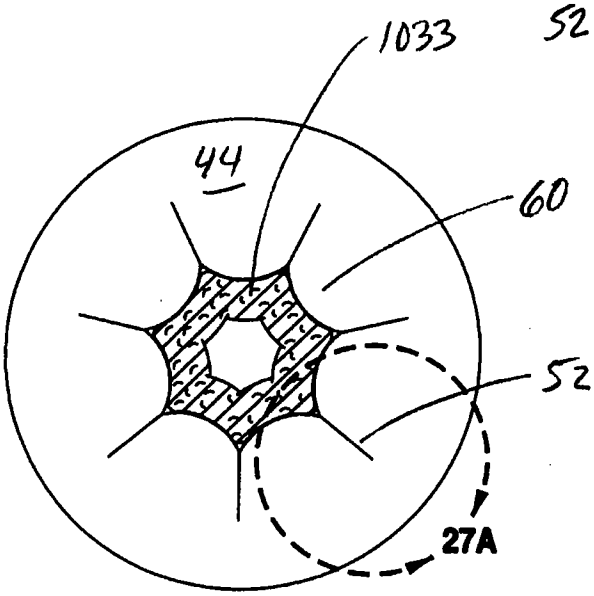

FIG. 27

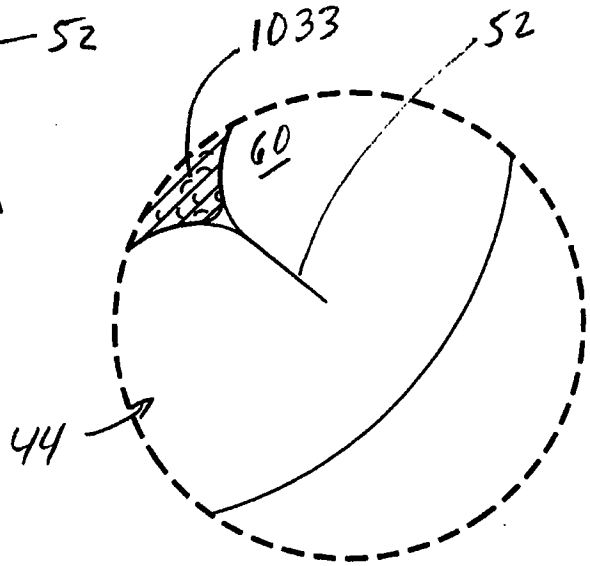

FIG. 27A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/059666

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/09047 A (FORSELL PETER [CH]) 24 February 2000 (2000-02-24) page 23, line 24 - line 29; figures 11-14,28	1-12, 14-21
X	US 6 102 922 A (JAKOBSSON ARNE [FR] ET AL) 15 August 2000 (2000-08-15) column 6, line 15 - column 8, line 54; figures 1-7	1-12, 14-21
P,X	FR 2 921 822 A (BRANCHE DOMINIQUE [FR]) 10 April 2009 (2009-04-10) page 7, line 10 - page 8, line 4; claims 8-12; figures 1,10 page 10, line 11 - line 17	1-12, 14-21
A	WO 2004/019671 A (INAMED MEDICAL PRODUCTS CORP [US]; BIRK JANEL [US]) 11 March 2004 (2004-03-11)	

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 January 2010	02/02/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Sánchez y Sánchez, J

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/059666

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17

A system for regulating an organ or duct, comprising:
-a band having a first end and a second end;
-at least one cushion segment coupled to the membrane and disposed on the proximal region of the band; and
-a mechanism for enabling adjustment of an inner circumference of the loop configuration.

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2. claims: 18-21

A system for regulating an organ or duct, comprising:
-a band having a first end and a second end;
-a contact region disposed between the first end and the second end of the band;
-the inner circumference of the loop configuration having a generally star-shape defined by the contact region; and
-a mechanism for enabling adjustment of the inner circumference of the loop configuration.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/059666

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 0009047	A	24-02-2000	AT	383834 T	15-02-2008
			AT	294553 T	15-05-2005
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FR 2921822	A	10-04-2009	NONE		
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			BR	0306183 A	19-10-2004
			EP	1553878 A2	20-07-2005
			MX	PA05002361 A	30-09-2005
			US	2005192531 A1	01-09-2005